facility during its mammography medical outcomes audit was a highly controversial area and generated a diverse number of comments. Five comments stated that FDA should collect audit results and publish the information in aggregate form for the public's information. Two additional comments argued that interpreting physician performance data should be made available to any third party or examinee.

On the other hand, 25 comments urged that FDA ensure confidentiality of medical outcomes audit data either through Federal legislation or under the MQSA. Thirteen comments sought to protect the data by making it available only for internal purposes and restricting its submission to FDA and other agencies. One respondent expressed concerns relating to the use of data by third parties, such as facilities, radiologists, and patients. The comment went on to say that, in the instance of a law suit, all such information would be subpoenaed. Five comments stated that due to lack of common definitions and public understanding of the statistics most likely to be captured in the medical outcomes audit, such data should not be made available to any person not affiliated with the facility. Nine other comments agreed that medical audit data should not be shared with others outside the facility, even though they agreed that valuable use can be made of the medical audit within the facility in assessing the accuracy of interpretations. Two comments argued that, unless false negative cases are required to be included in the medical outcomes audit and also protected from discovery, there will be incentives to conduct poor quality audits. Finally, one comment stated that medical outcomes audit requirements inevitably will increase third-party requests for medical audit data in order to select providers.

FDA recognizes the very sensitive nature of the issue of confidentiality of mammography medical outcomes audit data. Under the final regulations, there are no requirements for dissemination or reporting of the data to public bodies or other agencies, including FDA. There is, however, a requirement that each facility establish and maintain a system to conduct followup and make that system available for review by the inspector. Followup is required for all positive mammograms and for those patients who are known to have developed breast cancer after having had a mammogram at the facility. There is also a requirement for internal facility review of these data. FDA believes these regulations ensure the establishment and use of medical outcomes audit data to help protect the public health without necessarily jeopardizing the confidentiality of such data or the incentives facilities and practitioners have to use these data to improve performance. Future regulations are possible in this area.

(Comment 549). Fifteen comments wondered if radiologists could refuse to allow an inspector to copy audit data in addition to visually reviewing it. As discussed previously, FDA does not intend to have inspectors obtain photocopies of medical outcomes audit information. The agency is requiring inspectors only to verify that systems are in place for the facility's use as part of a quality assurance program (see earlier discussion in the preamble to the proposal at 61 FR 14875).

c. *General requirements (§ 900.12(f)(1))*

This paragraph requires facilities to establish and maintain a system for collection and review of outcome data and correlation of pathology results with initial mammographic results. The active collection and followup of data are to focus on positive mammograms with correlation between pathology results and interpreting physician's initial mammographic interpretation.

(Comment 550). Overall the comments about this paragraph were generally positive. Eight comments stated that the requirement would be beneficial to mammography facilities and staff. A small number of comments advocated that followup data be collected for all abnormal mammograms, including those requiring additional imaging before a final mammographic interpretation can be made.

FDA notes that the current language of the final regulations states that a system is to be in place to collect and review outcome data for all mammograms with required followup for positive mammograms. Although followup is required only for positive mammograms, facilities that wish to follow all their cases are encouraged to do so. Future MQSA regulations may include such a requirement for broader followup, including for those mammograms requiring additional imaging before determination of a final mammographic result.

Followup for patients with abnormal mammographic results has been conducted successfully by several different groups, including the National Cancer Institute Breast Cancer Surveillance Consortium, CDC, individual groups of radiologists, and on a statewide basis in Colorado. Followup for all patients with abnormal mammographic results, or symptomatic for breast cancer, or requiring additional imaging studies was successfully accomplished in Colorado through the Colorado Mammography Advocacy Project (CMAP).

As mentioned previously under the discussion on the use of the mammography medical outcomes audit as an alternative approach to design and process-based regulations, the National Cancer Institute's Breast Cancer Surveillance Consortium has also established a major research project to understand the full effect of breast cancer screening on cancer outcomes. Data on breast cancer screening practices from nine sites across the country are being linked to population-based cancer registries. By 2000, the database will contain information on nearly 3.2 million mammographic examinations and over 24, 000 cases of breast cancer. Standardized procedures and tools were created and are being tested by the surveillance consortium that will assist mammography facilities in data collection and auditing. Results and outcomes of the consortium will help establish performance standards for mammography and FDA will evaluate these for appropriateness for future standards under MQSA.

CMAP is a centralized data management system that conducted followup for all women with abnormal mammograms and women with symptoms of breast changes. CMAP also prompts return for regular rescreening through a series of reminder letters to women and their physicians. This system involves voluntary participation of mammography centers, with most facilities in the greater Denver metropolitan area participating. CMAP services were also offered to some or all patients outside of the metropolitan region. The same tracking and followup and screening reminder methods were used at these facilities as for those in the Denver metropolitan area. Data collection for individual patients, facilities, radiologists, surgeons, and referring physicians is governed by stringent standards for confidentiality. During the 8 years of operation of CMAP, the Program ensured that there were no breaches in confidentiality protocols. Followup includes collection of all information about diagnostic procedures performed to evaluate mammographic abnormalities. Currently, CMAP is tracking more than 200,000 women and more than 300,000 mammograms with approximately 3 percent falling into the ''positive'' category based on radiologists' mammographic interpretation. The system has documented screening

compliance rates in excess of 85 percent and improved outcomes associated with the diagnosis of breast cancer. Specifically, women tracked by CMAP and diagnosed with breast cancer had smaller tumor sizes and earlier stages at detection when compared to a cohort of women with breast cancer who had not received the level of tracking and followup performed by CMAP.

(Comment 551). Twelve respondents supported the FDA requirement for collection of outcomes data, but requested that FDA establish guidelines for the content of the audit and the audit process in order to ensure comparability of medical outcomes data. In contrast, three comments supported the current FDA position to establish only very general requirements for the medical outcomes audit.

In the absence of any consensus standards for either mammography outcomes or data collection methods, FDA has chosen to defer proposing these parameters and methods until more research has been completed and clear guidelines can be formulated for mammography centers.

Despite the general support for the medical outcomes audit, 28 comments expressed concerns that there is no consensus on measures of mammographic efficacy. As discussed above, FDA acknowledges the lack of substantive research on appropriate and accurate measures to assess accuracy of mammographic interpretation and, therefore, has not required specific data to be collected for the medical outcomes audit. Instead, the agency has established a general requirement that mammography facilities have a system in place to collect and review outcome data for all mammograms. Followup is mandatory only for positive mammograms and for patients who were previously screened at a facility and were subsequently found by that facility to be diagnosed with breast cancer.

In addition, the same 28 comments maintained that there was no evidence that performance feedback about mammography outcomes affected the quality of care. In fact, however, the agency notes that there are several articles in peer-reviewed journals indicating that performance feedback is an effective strategy to issue positive behavior change (Ref. 3).

(Comment 552). Many comments expressed concern about the impact on audit results of serving diverse populations of patients. It was recommended that FDA keep such variations in mind when more clearly defined medical outcome standards are established in the future.

FDA acknowledges the importance of this point and will take population diversity into account in the future development of more specific audit parameters.

(Comment 553). Three comments stated that the medical outcomes audit requirement emphasized detection of false positives and expressed the opinion that this was a meaningless outcome. Three more stated that the most important measure was the rate of false negatives.

FDA notes that the final regulations do not require reporting of either false negatives or false positives. The emphasis is on collecting followup data for all patients with positive mammographic findings and for patients who received mammography at a facility and were later determined to have breast cancer. Such followup may yield a number of statistics, including false negatives and false positives.

NMQAAC has suggested that FDA provide reference articles to which facilities could refer if they wanted to compare their own statistics with those of other practices. FDA supports this type of educational outreach and intends to list such references in *Mammography Matters* as they become available. NMQAAC also noted that future revisions of the regulations may require specific performance standards to be issued for mammography once scientific evidence supports such performance standards. The agency agrees that such future developments are possible. However, the current regulation requires followup only for patients with positive mammograms as defined by the assessment categories of ''suspicious'' and ''highly suggestive of malignancy'' and for patients who received mammography at a facility and were later determined to have breast cancer.

(Comment 554). Twenty-seven comments expressed concerns about burdens imposed by the FDA requirement for medical outcomes audit. The burdens included both financial costs of conducting the audit and concerns about staff time to collect the outcomes data. A subset of these comments specifically cited costs associated with the need for sophisticated computerized systems and an increase in clerical staff in order to accomplish the amount of followup required by the regulation.

FDA notes that the number of patients requiring followup (i.e., those mammograms assessed as ''highly suggestive of malignancy'' or ''suspicious'') should be relatively small compared to the general population of women screened at a given mammography facility. In fact, data from CMAP and the other programs cited above suggests that an average of 3.0 percent to 5.0 percent of the total population of patients receiving mammograms at a facility will require active followup. While FDA recognizes that there may be some increase in costs associated with staff time to conduct such followup for all positive mammograms and patients subsequently diagnosed with breast cancer, the benefits of followup are considered to outweigh the costs. In addition, the small number of patients requiring intense followup will not place an undue burden on an individual mammography facility when it is measured against the education and experience acquired by facility personnel. The information gained by staff has been shown to have a positive impact on interpretation skill. Feedback about patients with positive mammograms is extremely important information for both radiologists and technologists. Finally, it was the general consensus of the members of NMQAAC that the benefits of medical outcomes outweighed the costs, especially when one considers the small number of cases the current regulations will affect and data from centralized mammography tracking systems, such as the CMAP, which indicated that costs of followup can be minimized. One Committee member also noted that such followup actions could reduce costs associated with medical liability actions.

(Comment 555). Sixteen comments assumed that the medical outcomes audit would require computerized systems and more clerical help, thereby resulting in increased costs.

FDA notes that a computerized tracking system is not required by the final regulations. In fact, many facilities rely on a manual notecard tickler file to ensure appropriate and timely followup for eligible patients. Some facilities have joined a consortium of mammography centers where followup can be accomplished by a centralized data collection effort. Centralization of followup was designed and implemented very successfully for CMAP, with significant economic benefits and opportunities for data comparisons between one facility and the aggregate of all participating facilities. Utilization of unique identification numbers for patient, facility, referring physician, radiologist, and surgeon preserved confidentiality. Information on the type of data to collect and methods of data collection and interpretation will be forthcoming from FDA.

(Comment 556). Three comments asserted that the responsibility for followup should remain with the surgeon and/or referring physician.

FDA agrees that followup by the referring physician or surgeon may well be the most effective way to communicate with patients and collect outcome data. However, the agency's authority under the MQSA is focused on mammography facilities. FDA cannot establish audit or followup requirements for physicians who do not work as interpreting physicians in mammography facilities.

(Comment 557). One comment suggested that certified facilities be required to share patient outcome data with other certified facilities, especially if that information is necessary in order to complete the medical outcomes audit.

FDA has no evidence at this time that facilities are unwilling to share followup information with other facilities that have treated their patients. Upon implementation of the final regulations, FDA will monitor this cooperation and determine if there is a need for such a requirement in subsequent regulations.

It was requested that FDA define 'correlation' of mammographic results with pathology results. FDA has addressed this in the comments on § 900.2(bb) of the final regulations.

d. *Data collection (§ 900.12(f)(2))*

(Comment 558). This provision requires that data be collected on an ongoing basis for at least all patients with positive mammograms. The majority of the comments related to this paragraph suggested that the regulations require surgeons, referring physicians, and/or pathology laboratories to submit outcomes data to the mammography facility rather than requiring proactive followup by the facility for all positive mammograms.

FDA agrees that such reporting would facilitate the efficient collection of accurate outcomes data. FDA has taken actions to encourage other medical entities to voluntarily provide this data (Journal of the American Medical Association, 1995), but as noted above, FDA's authority under the MQSA focuses on mammography facilities. FDA cannot require other entities or health care practitioners to collect data and forward it to mammography facilities.

(Comment 559). One comment stated that it ''was not right to force a physician to file statistics with FDA just for statistics sake.''

FDA believes that it is important to point out that the final regulations do not require reporting of any medical outcomes audit statistics to FDA. If such requirements are established in the future, it would only be because it was justified by public health benefits and not ''just for statistics sake.''

(Comment 560). A number of comments raised concerns about the medical-legal implications of collecting outcomes data and some of these urged FDA to mandate audit protection for every facility in every state. Concerns were raised that the data could be subject to subpoena, used against facilities in malpractice claims, or evaluated by third-party payers to award contracts. Discussion among members of NMQAAC, on the other hand, indicated that collection and review of data does result in improved breast cancer detection outcomes and can also serve to protect a facility in the instance of a legal claim.

Although State laws on protection of medical audit data do vary, FDA believes such information is protected from use against facilities or physicians in the majority of cases. The Committee supported the regulations as they are currently written. As stated previously, the regulations only require that a system be in place to conduct followup and that such followup would be required for all positive mammograms. The regulations do not require disclosure of any outcomes data to FDA or any other entity outside the facility. The agency has concluded that the final regulations strike the proper balance because the benefit of audits in improving accuracy of interpretation outweigh concerns about forced disclosure to third parties.

e. *Frequency of audit analysis (§ 900.12(f)(3))*

This paragraph establishes guidelines for the frequency of the medical outcomes audit.

(Comment 561). The majority of comments relevant to this point supported an annual audit of medical outcomes, but also recommended that the audit period end 6 to 12 months prior to the date of the audit in order to ensure collection of complete patient information. FDA recognizes the need for adequate time to elapse in order to collect all relevant data. In response to the comments, the provision was amended to clarify that the audit analysis may be completed up to 12 months following the close of the audit period. This additional time for completion of followup was supported by NMQAAC. However, because the requirement is to do an annual audit, a subsequent audit period will be in effect during the time the facility completes followup for the previous medical outcomes audit period.

Comments also recommended requiring quarterly review of audit data by interpreting physicians. FDA established the requirement for annual review of these data in order to maximize the number of cases eligible for followup and data analysis. Facilities are free to review their audit data at more frequent intervals if that is useful or desirable for that practice. FDA notes, however, that quarterly audit review may not yield sufficient numbers of cases for performance of valid statistical analyses.

Finally, one comment asked what was meant by individually and collectively' for review of medical outcomes audit data. FDA has revised the provision to clarify that the medical outcomes audit data is to be evaluated by the reviewing interpreting physician for the entire facility and for each individual radiologist reading mammograms for the facility.

f. *Reviewing interpreting physician (§ 900.12(f)(4))*

This paragraph requires that each mammography facility designate at least one interpreting physician to review medical outcomes audit data at least annually. This individual will also be responsible for analyzing results and identifying issues based on these results and recording any followup actions.

(Comment 562). Eight comments expressed concerns about the utility and feasibility of conducting medical outcomes audit reviews for individual physicians. These comments reasoned that the numbers would be so small that findings would not be of practical or statistical significance, and that such analyses would also be resource intensive.

FDA acknowledges these concerns, but expects that, over time, adequate data will be available for individual interpreting physicians that will become meaningful and will allow tests of statistical significance.

(Comment 563). Five comments supported the proposal to include 'taking corrective action and documenting such actions' in the requirement, while two others argued that this would not always be possible.

Review of these comments and discussions with NMQAAC prompted FDA to change the wording to recognize that the reviewing interpreting physician may not always have authority to institute corrective actions. As revised, the proposed regulation requires the reviewing interpreting physician to document what, if any, followup actions were taken following review of the individual and aggregate medical outcomes audit data.

(Comment 564). Nine comments noted that facility performance monitoring and corrective actions were not defined in the regulations and, therefore, this provision is unclear.

FDA agrees and has deleted these terms in revising the language of this provision.

(Comment 565). Finally, one comment recommended that the reviewing interpreting physician should also be the individual responsible for overall facility quality assurance.

FDA does not believe that this dual role is necessary or beneficial for every facility, e.g., a physician who is best suited for responsibility over audits may not be onsite sufficiently often to also be responsible for overall quality assurance. Although the final rule would permit a facility to designate the same person for both responsibilities, it is not required.

7. Mammographic Procedure and Techniques for Mammography of Patients With Breast Implants (§ 900.12(g))

This paragraph implements the MQSA provisions that require FDA to establish ''standards related to special techniques for mammography of patients with breast implants'' (42 U.S.C. 263b(f)(1)(H)).

a. *Breast implant inquiries (§ 900.12(g)(1))*

As proposed, this paragraph required each facility to have in place a procedure to inquire if an examinee has a breast implant at the time of mammography scheduling.

(Comment 566). More than 110 comments opposed making this inquiry at the time of scheduling. Reasons for the opposition included: privacy concerns of the patient, the fact that the patient may not be the person scheduling the examination, and the belief that the best way to obtain this information is by having the technologist question the patient at the time of the examination. Eleven comments supported this requirement, reasoning that this would aid in efficient scheduling and urged FDA to publicize the need for implant patients to inform the facility of their situation at the time of making an appointment.

After reviewing all comments and discussing this issue with NMQAAC, FDA has revised § 900.12(g)(1) to require all facilities to have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination, but not necessarily at the time of scheduling. Those facilities that believe it is important to identify breast implant patients at the time of scheduling, in order for the facility to allot the correct amount of time for the study, are free to do so. The comments indicate that many facilities will choose to use the patient questionnaire to obtain this information or have the technologist question the patient prior to the examination.

(Comment 567). Several comments stated that facilities should have the option of referring breast implant patients to facilities where such examinations are done regularly.

FDA agrees with these comments and notes that there are no regulations requiring facilities to perform studies on patients with implants. For those facilities electing not to perform mammography on patients with breast implants, FDA strongly recommends that they develop a mechanism to inform referring physicians and patients of this fact. This will decrease the chances of such patients arriving at a facility that does not ordinarily perform breast implant studies.

(Comment 568). Two comments suggested establishing a minimum volume for these types of examinations in order to concentrate them at facilities that are the best for this purpose.

FDA recognizes that increased experience with imaging patients with breast implants is likely to develop expertise. However, the agency believes that it is in the best interest of all concerned to have high quality mammography performed in as many facilities as possible. It is possible that one technologist at a particular facility may have had additional training in techniques for imaging such patients and be able to do excellent examinations despite relatively low numbers of such patients. It is not the intent of the MQSA to arbitrarily restrict access to mammography services.

b. *Maximizing the visualization of breast tissue for patients with implants (§ 900.12(g)(2))*

This paragraph requires that patients with breast implants undergoing mammography have mammographic views to maximize the visualization of breast tissue, except where contraindicated or modified by a physician's directions.

(Comment 569). Nine comments stated that it is important to take additional and specialized views of the implanted breast in order to achieve maximum visualization of tissue. The authors asserted that a minimum standard, such as requiring Eklund views, should be set. One contradictory comment stated that requiring mandatory views would cause unnecessary irradiation because not every implant can be displaced as in the Eklund procedure.

FDA and NMQAAC agree that, currently, the Eklund procedures, including appropriate individualized views, provide the best mammographic means to visualize breast tissue for most women with implants. The agency and the committee also recognize that other methods may exist that would be preferable in particular cases. Because breast implant imaging is evolving, the agency believes that it would be premature to limit, by regulation, this imaging to only one technique. FDA does not believe that this regulation, as written, will result in unnecessary irradiation of patients because it allows facilities to customize the study to the individual patient.

NMQAAC recommended deleting the phrase ''and optimize breast cancer detection'' as being redundant. FDA agrees and has deleted the phrase from the final provision.

c. *Onsite supervision of mammograms of patients with breast implants (§ 900.12(g)(3))*

FDA received almost 300 comments opposing this proposal, which would have required that mammograms of patients with breast implants be supervised by an onsite interpreting physician. Reasons for the opposition included: Severe scheduling and access problems if an interpreting physician had to be present, no demonstrated medical need for an onsite physician, and the belief that technologists are capable of performing implant examinations without the supervision of an interpreting physician. Four comments supported the section as proposed, stating that it was important to have an interpreting physician onsite to check the quality of the images.

FDA has been persuaded by the comments and subsequent discussions with NMQAAC that requiring an onsite interpreting physician would result in a decrease in access to high quality mammography services for women with breast implants without a significant improvement in the quality of care. Therefore, FDA has deleted this provision.

8. Consumer Complaint Mechanism—Facility Standard (§ 900.12(h)) and Accreditation Body Standard (§ 900.4(g))

These paragraphs, as proposed, establish a process for facilities and accreditation bodies to collect and resolve serious consumer complaints. It provides patients with a mechanism to report what they believe to be seriously deficient mammography services and gives them the opportunity to have their complaints heard, investigated, and resolved.

Section 900.12(h), under facility standards, establishes requirements for facilities with respect to collecting and resolving serious consumer complaints, while § 900.4(g), under accreditation body standards, establishes requirements for actions that accreditation bodies must take to resolve consumer complaints referred to them.

Many of those who commented on the proposed regulations seemed unaware that different aspects of the complaint mechanism were addressed in these two separate paragraphs, and unaware that both sections should be read with reference to the definitions section of the regulations at § 900.2. Because the comments on these separate provisions tended to be similar, and in order to help illustrate the connection between them, FDA concluded that it would be most efficient to address public comments on the complaint mechanism sections of the proposed regulations as a group.

As the consumer representatives on NMQAAC noted, of all of the comments on the complaint mechanism, only two were from consumers. Almost all of the comments were from representatives of mammography facilities.

(Comment 570). Several comments agreed with FDA that facilities should have the flexibility to develop their own complaint mechanism and institute their own procedures for response and resolution. One comment supported the requirement that facilities develop a system for collecting and resolving serious complaints about mammography services and the proposed definition of serious complaints. Two comments, including one from a breast cancer advocacy organization, expressed support for the consumer complaint provision that FDA proposed.

One comment noted concern that there is no rule requiring feedback by facilities to FDA about an accreditation body. The comment suggested that FDA implement a communication mechanism for facilities to register complaints/comments with FDA about the accreditation body. The comment recommended that the mechanism guarantee followup, similar to the provision establishing a consumer complaint mechanism.

FDA believes mechanisms for facility feedback to FDA already exist. Facilities that wish to comment about accreditation bodies may contact FDA's DMQRP (address above) and will receive a response. In addition, the statutory requirement for FDA to audit the performance of accreditation bodies through inspections of selected facilities establishes additional opportunities for review and feedback.

(Comment 571). Two comments discussed the manner in which accreditation bodies might implement the complaint resolution process. One suggested that serious consumer complaints should be handled by an ACR Peer Review process. Another suggested that accreditation bodies could form boards to receive unresolved serious complaints.

FDA notes that the final regulations prescribe no particular method for accreditation bodies to use, believing that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients they serve. Establishing specific groups to review unresolved complaints is one acceptable method for fulfilling this requirement.

(Comment 572). One comment recommended that, because accreditation bodies have no enforcement authority other than to revoke or deny accreditation, FDA or the State certifying entity should retain authority to investigate consumer complaints.

In response, FDA notes that nothing in the MQSA or the regulations precludes FDA or a State from investigating complaints. However, the agency believes consumer complaints will be addressed most effectively and efficiently by a three-tiered approach. First, the complaint should be registered at the facility, where there is the greatest chance for resolution. Second, serious complaints that have not been resolved at the facility should be directed to the accreditation body. And, third, the accreditation body can forward serious complaints to FDA. Although consumers may choose to complain to the facility, the accreditation body, or FDA, the intent of these mechanisms is to resolve difficulties quickly at the level closest to the consumer.

(Comment 573). One comment suggested a name change for the consumer complaint mechanism. The author supported the proposed requirement, but preferred the use of either ''consumer comment mechanism,'' or ''consumer feedback mechanism'' to encourage feedback on positive mammography experience(s).

FDA and members of NMQAAC agree that the term ''complaint'' has negative connotations and may not encourage well-deserved positive comments. The statute, however, requires FDA and NMQAAC to develop a mechanism for the investigation of ''consumer complaints.'' Consequently, FDA adhered to the terminology in the statute.

(Comment 574). FDA received seven comments requesting additional guidance and detail about consumer complaint procedures. Five comments suggested that guidance documents be made available for facilities to follow in generating their system for collecting and resolving complaints, including directions for consumers who wish to file a complaint with the facility's accreditation body. One comment suggested that FDA develop a standardized plan, with appropriate forms to review and evaluate each facility's consumer complaints. One comment supported the proposed definition of a serious complaint, but noted that most complaints deal with Medicare and insurance reimbursements, or lack thereof.

FDA agrees that additional information will be helpful and members of NMQAAC have also strongly recommended that guidance be developed. The agency plans to develop such documents for facilities and consumers.

In reference to discussions in the proposal about cultural considerations, one comment noted that facilities cannot reasonably be expected to develop complaint procedures for all possible language, ethnic, and literacy backgrounds. FDA agrees that to require facilities to make such provisions would pose an undue burden. However, the agency encourages facilities to design their complaint mechanism procedures to be responsive to the particular needs of consumers they serve.

(Comment 575). Fourteen comments stated that the required consumer complaint mechanism increases costs.

FDA believes that the requirements for the complaint mechanism are minimal. Preliminary estimates indicate that the costs for establishing and implementing a system are not significant and that many facilities already have such systems in place. In addition, costs of establishing and implementing such systems are likely to be outweighed by the benefits to the facility resulting from better patient relations, enhanced reputation, and avoidance of costs related to unresolved complaints that may lead to litigation.

(Comment 576). Several comments expressed concern that some consumer complaints could unfairly jeopardize facilities and particular employees. These comments hypothesized a variety of situations: A facility's certification could be threatened by an examinee bent on vengeance (for example, if a false negative mammogram and an error in interpretation constitute serious complaints); certain employees could be singled out any time a complaint is

referred to a higher authority (the accreditation body); the technologist could be falsely accused of a myriad of issues pertaining to patient care. Another comment interpreted the proposed regulation to mean that patients with complaints must be contacted for their opinion on whether the facility's solutions are acceptable to them.

FDA foresees some situations in which a facility's certification may be threatened as a result of consumer complaints. For example, if serious complaints have been continuously ignored or left unresolved by the accreditation body or the facility, subsequent FDA investigations may demonstrate that the facility is unable or unwilling to comply with the MQSA standards. The agency is confident, however, that most facilities will make a sincere and effective effort to respond to valid complaints and does not expect that it will be necessary to consider suspending or revoking certificates for this reason, except in rare cases. In reference to concerns about personnel being unjustly accused, FDA notes that technologists are not ordinarily designated as the individuals responsible for the facility's management and operation. To the extent consumer complaints lead to improvement in performance of individual personnel, the quality of mammography is improved at that facility. With respect to the need to contact consumers about resolution of complaints, the agency believes such communication is a necessary part of resolving a complaint. If consumers believe the facility's solutions are unacceptable, they may contact the accreditation body or FDA, who will try to resolve the issue on a case-by-case basis.

(Comment 577). Seven comments noted their objection to additional policies and procedures for a consumer complaint mechanism. One comment noted that a mandatory facility complaint mechanism is superfluous because effective resolution of patients' complaints is already a component of proper patient care. Another comment noted that each facility can develop its own consumer complaint plan without any guidelines from the MQSA. Fourteen comments suggested that FDA simply accept the policies and procedures for mammography consumer complaints that are currently in use at each facility. If no policy and procedures are in place, the facility should establish one.

FDA agrees that, for the majority of facilities, effective resolution of patient complaints is already a component of proper patient care. In fact, under the interim rules, facilities are required to post an address where complaints can be filed with accreditation bodies, and maintain records of all complaints registered at the facilities. The requirements in the final regulations, therefore, should present little additional burden. Those facilities that already have procedures in place are unlikely to have to make any significant changes. Only facilities that do not have a system in place will be required to make any significant investment of resources. As discussed above, procedures are likely to benefit both the public health and the individual facility.

(Comment 578). One comment suggested that the facility should have the option to ignore a consumer complaint. This comment stated that facilities should be encouraged to handle complaints, but not required to do so.

Under the final regulations, a facility must establish a written and documented system for collecting and resolving consumer complaints. That system may include varying degrees of responsiveness to different kinds of complaints. A complaint about the temperature of the waiting room may be handled differently than a complaint about failure to receive notification of examination results. There may be certain types of complaints under its system that a facility decides do not merit additional resources beyond a verbal acknowledgment or response. However, the system must include a mechanism to provide consumers with a way to register serious complaints with the accreditation body. The consumer can use that information to take serious complaints to the accreditation body and inform the accreditation body that the facility made no attempt to resolve the complaint.

(Comment 579). One comment applauded the consumer complaint mechanism in theory, but questioned the wisdom of permitting the facility to determine whether the complaint is serious. The comment stated that facilities should be required to record all complaints and provide all consumers with directions for filing complaints with the facility's accrediting and/or licensing body. FDA does not believe that the facility independently determines whether the complaint is serious because the definitions of ''serious complaint,'' ''serious adverse event,'' and ''adverse event'' (see § 900.2) are the basis for such decisionmaking. Also, if consumers are not satisfied with the complaint resolution, they may complain directly to the accreditation body. A facility's system may require that records be kept for all complaints and that consumers be provided with directions for filing all complaints with the accreditation body if they choose to do so. However, tracking and providing the consumer with instructions about how to file a complaint with the accreditation body are required under the regulations only for serious complaints.

Nine comments recommended that all complaints should be handled on an individual basis at each facility, and that recordkeeping should be based on the protocol for that facility. Two comments noted the additional amount of paperwork the consumer complaint mechanism would generate, and one of these noted the possibility that facilities would be open to liability because of this mechanism.

FDA agrees that all complaints should be handled at the facility if possible, and that recordkeeping procedures can vary with each facility and each complaint, so long as tracking and accreditation body notification are established for serious complaints. If satisfactory resolution of the complaint cannot be achieved at the facility level, however, the consumer must have the option of taking the complaint to another level. In response to the concern about generation of paperwork, FDA notes that the requirement to track complaints has been in effect under the interim regulations since 1993 without any feedback indicating excessive paperwork. As to concerns for additional liability, the agency and members of NMQAAC have both noted that records that are required to be tracked are more likely to help facilities document that they responded to and resolved complaints. In addition, effective consumer complaint mechanisms allow facilities to identify problems and improve the quality of their services.

(Comment 580). One comment advocated that some safeguard addressing confidentially should be implemented before this and similar recordkeeping requirements are retained in the final regulations. FDA notes that consumer complaints are part of patient records and will be handled by facilities with the same care as other records relative to patients. Accreditation bodies are required to protect nonpublic information they receive from facilities and will not further disclose such information. FDA's public information regulations prohibit disclosure of patient records or information that would identify individual patients.

(Comment 581). FDA did not propose a requirement that facilities post a sign that explains how to file consumer complaints, although NMQAAC members supported such a requirement. Nevertheless, the agency received 28 comments, all on a form letter, opposing any requirement for posting of the complaint process, particularly with respect to addressing complaints to the accreditation body. These comments argued that such a notice will confuse patients and send mixed messages (e.g., this is a certified facility, but here's how to complain). One comment noted that the consumer complaint mechanism needs to be more clearly articulated in order to determine a mechanism for posting. The comment expressed concerns about promoting dissatisfaction with the screening experience.

FDA notes that facilities can develop their own posting mechanism if they chose to do so. In these cases, the facility could use messages such as: ''We care about our patients. If you have comments and/or concerns, please direct them to (the name of the person in the facility who is responsible for complaints).'' FDA notes that the name of the accreditation body is listed on the facility certificate, which the facility is required by statute to post prominently within view of patients.

9. Clinical Image Quality (§ 900.12(i))

This paragraph establishes that clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the facility's accreditation body.

This requirement did not appear as a separate provision in the proposal but was added to the final regulations to emphasize that adequate clinical image quality is to be maintained by the facility on an ongoing basis and is not something to be achieved only at the time of accreditation. FDA recognizes that this requirement may appear unnecessary or redundant. The stated purpose of the MQSA, to establish national uniform minimum quality standards for mammography facilities, presumes that all facilities will produce adequate mammograms on a regular basis. Specific statutory provisions, such as those requiring random clinical image review by accreditation bodies and the establishment of quality assurance programs at each facility to ensure clarity of images, reflect the drafters' intent to ensure quality mammograms for every patient. In addition, the interim regulations issued by FDA and these final regulations establish and support the need for maintenance of adequate clinical image quality at all times. However, FDA's experience with implementation of the interim regulations, and the impression the agency has received from some of the public comments, suggests that some facilities may view clinical image quality as important only or primarily in connection with the accreditation process. The agency has concluded that this critical standard for quality mammography should be stated explicitly in order to emphasize its critical importance and eliminate any chance of misunderstanding.

10. Additional Mammography Review and Patient Notification (Proposed § 900.12(i) (Final § 900.12(j)))

This paragraph requires a facility to cooperate with FDA in the investigation of concerns about the quality of the mammography performed by that facility and in notification of patients or the public, should the investigation justify such notification. As the result of the addition of the new § 900.12(i), Clinical image quality, this paragraph is now § 900.12(j) in the final regulations. The provision has been modified from the original proposal to clarify that this type of review is different from those performed either for accreditation, reaccreditation, or for random clinical image review. Additional mammography review is to be used in those cases where FDA has reason to believe that mammography quality has been compromised and may present a serious risk to human health. Depending on the individual circumstances, this review may be an onsite evaluation or may be performed through the mail. Procedures for performing additional mammography review will be developed by the accreditation bodies and approved by FDA.

If the agency determines that any activity related to the provision of mammography at a facility presents a serious risk to human health, § 900.12(j)(2) requires a facility to notify patients, their designees, their physicians, or the public of actions that may be necessary to minimize the risk. Such notification may be warranted, e.g., in cases where diagnoses of possible malignancy may have been missed due to grossly inadequate performance on the part of the facility. Patients, their designees, health care professionals, or the public may have to be notified so that they may take appropriate remedial action. For example, affected patients may wish to repeat examinations at another facility or a member of the public may be able to contact an otherwise unreachable patient.

(Comment 582). While seven comments supported these requirements as originally proposed, the authors of 26 other comments were concerned about possible abuse of the provisions. These comments requested more information and clear guidelines on how ''serious risk to human health'' would be determined and how the regulation would be implemented. One comment stated that the entire section was not needed and should be deleted. The authors of 25 comments stated that this section sounded like a consent decree without an appeals process. The comments also stated that the intent of this section was unclear.

FDA notes that even comments that expressed concern generally supported the need to investigate and to take appropriate action at facilities where there is a serious risk to human health. In response to specific comments, the agency first notes that patient notification will not always be an appropriate corrective action, even in cases where mammography services have been inadequate. In some cases, patient notification could result in unnecessary patient anxiety, without providing the patient with any plan of action that the patient could take to minimize her risk. The agency recognizes the important consequences to the patients, the public, and the facility of pursuing patient notification and would not initiate such action without full consultation with the accreditation body and the facility and only following review of the additional mammography review performed by the accreditation body.

Although NMQAAC agreed that the agency should exercise this authority with respect to facilities that are performing poorly, members of NMQAAC were unable to reach a consensus on guidelines for initiating patient notification. FDA's experience under the interim regulations may reassure facilities and the public that patient notification is not requested unless FDA has evidence, including review of clinical images by the facility's accreditation body, that indicates there is a strong likelihood that a significant number of mammograms taken by the facility were inadequate. In any given situation, notification will only be appropriate where the benefits of providing notice to women, who may wish to repeat the exam, outweigh any resultant risks, such as patient anxiety or the possible disincentive for future mammography screening. Because of the number of variables involved in any particular situation, FDA believes that the decision as to when a facility has sufficiently

serious problems to warrant patient notification is best made on a case-by-case basis. In the past 2½ years, two facilities have instituted limited patient notification after an investigation by the accreditation body and FDA.

The intent of this section is to assure the public that in those cases of suspected compromised mammography quality, an investigation is performed, and depending on the results of that investigation, appropriate corrective action is taken. If patient notification is the corrective action recommended by the accreditation body and required by FDA, the facility will have every opportunity to participate in designing and implementing that notification. As with any adverse accreditation body or FDA action, the facility has the right to have a determination about patient notification reviewed and appealed within the agency. If the facility does not voluntarily come into compliance or take steps the agency has determined are necessary to ensure quality mammography at that facility, FDA can initiate suspension or revocation of the facility's certificate. In those circumstances, the facility is entitled to a hearing under part 16 of the agency's regulations (see § 900.14) and hearing decisions are subject to judicial review. Contrary to the opinion of many respondents, therefore, FDA's determination that patient notification is necessary is subject to review and appeal.

(Comment 583). One comment opposed this section, asserting that FDA already performs clinical image reviews by randomly notifying the facility that they have so many days to send in certain mammograms.

FDA notes that the author of this comment mistakenly believed that random clinical image review and additional mammography review were the same. As previously stated, these two reviews are performed differently and address different issues and problems. Random clinical image review is performed as an evaluation tool by accreditation bodies in an effort to audit their own performance, and the performance of facilities they accredit. Additional mammography review is to be performed only in those cases where FDA believes there has been a compromise of quality sufficient to pose a serious risk to human health.

(Comment 584). Two comments stated that FDA should ask the accreditation body to investigate questionable facilities, but that the type of evaluation and the final decision should be left up to the accreditation body.

FDA continues to work closely with the accreditation bodies to coordinate all activities, especially those related to image review and mammography quality. Accreditation bodies are critical in establishing processes and parameters for additional mammography review at any particular facility and may be the first entity to discover information that indicates such a review is necessary. Nevertheless, decisions about whether additional mammography review or patient notification are necessary ultimately must rest with the agency.

(Comment 585). One comment questioned why FDA would not start this process as soon as a facility fails accreditation due to clinical image review.

FDA responds that accreditation clinical image review is an evaluation of the ''best'' images that a facility can produce and is scored against the accreditation body's highest standard. Failure to achieve the high quality standard does not necessarily mean that the facility's average images are of a quality likely to result in the misdiagnosis of significant abnormalities.

It is FDA's view that failure of accreditation or reaccreditation clinical image review does not automatically indicate that the facility's overall quality level has been compromised to such an extent that there is a serious risk to human health. Unless there is other information indicating such a risk, the agency does not intend to apply § 900.12(j) to this circumstance. The initiation of additional mammography review under this section is primarily intended to protect the public in circumstances where there is reason to believe an accredited facility is practicing in a way that may cause serious harm.

M. Revocation of Accreditation, and Revocation of Accreditation Body Approval (§ 900.13)

This provision describes the procedures that FDA will follow in the event a facility's accreditation is revoked by its accreditation body (§ 900.13(a)). It also outlines the facility's responsibility if FDA withdraws approval of its accreditation body (§ 900.13(b)). No comments were received on § 900.13(b).

(Comment 586). One comment supported § 900.13(a) as written while another comment stated that this section is unclear, and asked whether a facility is allowed to conduct mammography without accreditation. Another comment suggested that no FDA certification should continue in force after an accreditation body has revoked the accreditation of a facility.

FDA issues certificates, and only FDA can determine when a certificate is no longer in effect. Loss of accreditation does not automatically mean the loss of certification. In certain unique circumstances, a facility may remain certified though it lacks accreditation. For example, a facility may be certified through a provisional certificate to perform mammography before it is accredited (42 U.S.C. 263b(c)(2)) or retain its certification for some period of time following FDA withdrawal of its accreditation body's approval (42 U.S.C. 263b(e)(2)). Under the MQSA, if an accreditation body revokes the accreditation of a facility, the certificate remains in effect until such time as may be determined by FDA (42 U.S.C. 263b(e)(5)). FDA interprets the statute to give the agency discretion to find that the certificate should no longer be in effect once accreditation has been lost or to permit the facility to continue to perform mammography for some period of time following loss of accreditation. The language in the final regulation has been amended to reflect this discretion.

After revocation of a facility's accreditation, FDA may conduct an investigation into the reasons for the revocation. Following the investigation, the agency may take whatever action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan that may permit the certificate to remain in effect while the facility seeks reaccreditation. (In the event that the investigation convinced the agency that revocation of accreditation was not justified, FDA would have discretion to continue the certificate in effect while the original accreditation body reinstated the facility or another entity provided accreditation). Anytime FDA determines that the revocation was justified and the certificate should not continue in effect, the facility that has lost its accreditation may no longer perform mammography. The final regulation has been amended to clarify that a facility whose certificate is no longer in effect must cease to practice mammography.

(Comment 587). Three comments concerning this provision appear to have confused revocation of accreditation with revocation of certification. One suggested making the accreditation bodies responsible for appeals of revoked certificates, and two described facilities that purportedly were unable to operate for 2 years as the result of revocation of their certificate due to a single flawed image or the recommendation of the facility's accreditation body.

FDA does not have enough information about the specific cases referenced in the last comments to respond, except to note that an accreditation body does not have authority to revoke a certificate. In response to the first comment, the agency reiterates that suspension or revocation of accreditation is the responsibility of the accreditation body, and each accreditation body is required to have internal appeals procedures available to all the facilities it serves. Suspension of revocation of an MQSA certificate, however, is the responsibility of FDA. Such suspensions and revocations are governed by 42 U.S.C. 263b(i) and the regulation implementing that section in § 900.14. An accredited facility whose certificate FDA is seeking to suspend or revoke is generally entitled to a hearing before that action is taken in accordance with 42 U.S.C. 263b(i) and § 900.14. The agency wants to take this opportunity to clarify, however, that a facility whose certificate FDA determines to be no longer in effect because its accreditation has been revoked is not governed by 42 U.S.C. 263b(i) or § 900.14. In accordance with 42 U.S.C. 263b(e)(5), the certificate of a facility whose accreditation has been revoked remains in effect only until such time as determined by FDA. Although such a facility will be entitled to an opportunity for a timely hearing following a determination by FDA that the certificate is no longer in effect, it may not continue to practice mammography in the interim.

N. Suspension or Revocation of Certificates (§ 900.14)

This section sets forth the conditions under which FDA may suspend or revoke a facility's certificate.

(Comment 588). One comment supported this section as written, while another recommended that this section be revised to include the MQSA provision which authorizes States to conduct certification duties.

As noted earlier in this preamble, the subject of States as certifying bodies is beyond the scope of these regulations. Preparations are under way to draft regulations that will govern State agencies that wish to become certifying bodies.

(Comment 589). One comment recommended changing the word ''determines'' to ''believes.''

Suspension or revocation of a facility's certificate is an action against the facility that should be based on more than ''belief.'' FDA does not intend to take such action without making a determination that it is warranted.

Because there were so few comments on this section, it has been codified basically as proposed. The discussion in the preamble to the proposal at 61 FR 14877 through 14878 describes the provisions of this section in detail. FDA has added failure to provide information, reports, or records ''to the accreditation body'' as an additional grounds for suspension or revocation in § 900.14(a)(3). The agency has made this change to ensure that accreditation bodies have access to records, including clinical images, that are necessary for review. In many circumstances, the accreditation body's access to records is essential for it to fulfill its obligations under the statute and to advise FDA with respect to potential enforcement actons. A facility that refuses to supply such records makes it difficult, if not impossible, for the accreditation bodies and FDA to efficiently investigate or monitor mammography practices at that facility.

O. Appeals of Adverse Accreditation Decisions that Preclude Certification or Recertification (§ 900.15)

The title of this provision has been changed to better reflect the fact that it describes the procedures for appealing adverse accreditation decisions that preclude a facility from becoming certified or recertified.

(Comment 590). One comment supported this section as written, and another comment questioned whether a facility can submit additional information in its appeal to FDA, noting that ACR does not consider any additional information from a facility and bases its appeal findings on rereview of the films from the facility that were originally evaluated.

When appealing an adverse accreditation decision, FDA will consider and evaluate any information provided by the appealing facility that may bear on the outcome of the appeal, in accordance with the governing regulations identified in the next paragraph.

(Comment 591). One comment suggested adding ''or reaccredited'' in addition to, ''has failed to become accredited.''

FDA agrees that the addition of ''reaccredited'' would add clarity. Another comment recommended that there be a timeframe for appeals. The MQSA establishes that the procedures in 42 CFR part 498 are to be followed by FDA for appeals. These regulations contain the timeframes to be followed for appeals under the MQSA.

P. Appeals of Denials of Certification (§ 900.16)

The comments that requested clarification about the relationship between revoked accreditation and continued certification encouraged the agency to explicity address the issue of facilities that have received accreditation but are denied a certificate. FDA has added a new provision to clarify that the statute provides the agency with discretion to deny certification to a facility that has been accredited. As discussed previously in connection with the section on reviewing applications for certificates, FDA ordinarily will issue a certificate to a facility that has proof of accreditation by an approved accreditation body. This has been the agency's practice in the past and the agency intends to continue its reliance on the professional bodies that are expert in these reviews.

However, there may be situations when the agency has access to information that was not available to the accreditation body or when the agency has other reasons to disagree with that body's determination that the facility applying for a certificate will practice quality mammography. In these unusual circumstances, FDA has authority to deny a certificate. The new provision sets forth the grounds that FDA will use as the bases for such denials: A finding that the facility is not likely to comply with the quality standards; a finding that the facility is not likely to permit inspections or provide access to records and information in a timely fashion; or a finding that the facility was guilty of misrepresentation in obtaining accreditation. These grounds are parallel to those that are the statutory bases for suspension or revocation of a certificate. FDA believes that it is in the interest of public health to ensure that such facilities are not permitted to begin practicing mammography rather than automatically granting a certificate that the agency must later seek to revoke.

The new provision also provides appeal rights for facilities that are denied a certificate. These procedures are the same as those set forth for reconsideration and appeal of an adverse accreditation decision in § 900.15. The procedures are mandated by the statute under 42 U.S.C. 263b(d)(2) and include the right to request a formal hearing from the Departmental Appeals Board of the Department of Health and Human Services.

Q. Alternative Requirements (§ 900.18)

Section 900.18 establishes procedures for approval, extension, and withdrawal of alternatives to the quality standards of § 900.12. Such alternatives can be approved if, among other things, the alternatives provide at least as great an assurance of quality mammography as the original standards. The alternative requirement procedure allows the agency to permit the practice of mammography to benefit rapidly from improvements and advancements without the need to first go through the often lengthy process of amending the regulations. When added to the interim requirements through the amendments of September 30, 1994 (59 FR 49808), no public comments were received. This section was incorporated into the final regulations with only minor changes. A few comments were received.

1. General Comments on Alternative Requirements

(Comment 592). Two comments supported this section, one referring to it as a ''most sensible approach,'' but urged monitoring of the use of the alternatives after approval. A third comment suggested that manufacturers be required to provide documentation of approved alternatives to potential purchasers and that copies be available at the facility for review by the physicist and the inspector. A fourth comment urged removal of this section, stating that no variation in meeting the requirements should be allowed.

FDA believes that this process is needed to avoid the danger of discouraging advances in mammography and freezing technology at the present level. If the standards had to be amended to permit use of an advance in methods, training, or technology, the time required for the amendment might well discourage members of the public from attempting improvements. The agency does not believe that it is necessary to make the third comment a regulatory requirement. Manufacturers will find it difficult, if not impossible, to sell equipment that does not meet the requirements or an approved alternative. Because facilities will demand such documentation and will be required to produce it to pass surveys or inspections, FDA concludes there will be sufficient incentive to provide documentation without issuance of a regulation. The agency also notes that copies of applications, amendments, and extensions of alternative standards will be available to the public in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Dockets Management Branch is open to the public between 9 a.m. and 4 p.m., Monday through Friday.

2. Approved Requests for Alternative Standard Notification (§ 900.18(d)(2)(ii))

(Comment 593). One comment recommended that the justification level for an alternative requirement in this paragraph should be changed from the benefit being so great that the time required (typically more than 1 year) for an amendment would be ''an unjustifiable risk to human health'' to a standard that established that the alternative requirement ''provides a benefit to human health.''

FDA believes that the criterion suggested by the comment could be too low for some ''benefits,'' and has retained the provision as proposed.

3. Summaries (§ 900.18(d)(3))

(Comment 594). One comment stated that the requirement for providing summaries of alternative standards to NMQAAC should be deleted because NMQAAC does not have authority to approve or reject actions of FDA in such matters.

FDA agrees that NMQAAC does not have approval authority in such matters, but it does have the responsibility to advise FDA on matters related to FDA's development and implementation of standards. Because the agency cannot gain the benefit of this advice on alternative requirements without informing NMQAAC about the alternatives, FDA does not accept this comment.

4. Applicability (§ 900.18(f))

This paragraph describes the applicability of an alternative requirement. The proposal limited the use of the alternative to the applicant, with the exception of alternative requirements approved for manufacturers of equipment, which would apply to all users of the equipment. Under the proposal, others desiring to make use of other alternative requirements would have to apply separately.

(Comment 595). Four comments stated that FDA should reserve the authority to extend any approval beyond the applicant. A fifth comment went further and advocated automatic extension of an approved alternative requirement to all interested parties. FDA originally placed the limitation on the approval of alternative requirements in order to assure itself that the conditions that prompted the approval of the original application also applied for other applicants.

In light of these comments and after further consideration, the agency has concluded that the limitation would impose an unnecessary resource burden on applicants and FDA. Such a burden is not warranted by the low probability that an approved alternative requirement should not be extended to other interested and similarly situated parties. However, because the program is relatively new and the circumstances that may trigger requests for alternatives are so varied, FDA has concluded that it should review the appropriateness of each possible extension instead of making it automatically approved as suggested in the fifth comment. Accordingly, § 900.18(f) has been revised to permit expansion of the approval of the alternative requirement to other entities, but only after FDA has determined that this would be an effective means of promoting the acceptance of measures to improve the quality of mammography.

5. Other Changes

FDA has also made a change in the administrative procedures included in § 900.18, realizing that the level of delegation of authority to approve alternative requirements may vary with time or organizational changes. Thus, the specific references to approval by the Director of DMQRP have been replaced by general references to approval by FDA.

R. Conforming Amendments

Conforming amendments were made to 21 CFR 16.1 to add §§ 900.7 and 900.14 to the list of provisions under which regulatory hearings are available.

IV. Environmental Impact

The agency had determined under 21 CFR 25.34(c) that this action as proposed is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

The agency has conducted analyses of the final rule, and has determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes. FDA's analysis, as summarized in the remainder of this section, demonstrates that the final rule constitutes an economically significant rule, as described in Executive Order 12866. The agency has further determined that the final rule may have a significant economic impact on a substantial number of small entities. This discussion, therefore, along with the other relevant sections of this preamble and the agency's final Economic Impact Analysis (available at the agency's Dockets Management Branch), constitute the agency's final regulatory flexibility analysis as required under the Regulatory Flexibility Act. Similarly, because this rule is expected to result in expenditures that exceed $100,000,000 in at least 1 year, these documents also comprise the agency's assessment of anticipated costs and benefits under the Unfunded Mandates Reform Act. The final economic impact analysis also includes all references.

FDA presented a summary of its preliminary economic analysis in the preamble to the proposed rule (61 FR 14856). That summary discussed the potential costs and benefits of the proposed rule and described the findings of a more detailed industry analysis conducted by FDA's contractor, the Eastern Research Group (ERG). In response, the agency received numerous comments that addressed economic issues. FDA has examined and evaluated the reasoning and data presented in these comments and has incorporated many of them into its revised analysis of the final rule. The following discussion provides a summary of these impacts and presents the agency's responses to the relevant public comments.

A. Incremental Costs

For its analysis of the incremental costs of the proposed regulation (''Cost and Benefit Analysis of Regulations Under the Mammography Quality Standards Act of 1992''; preliminary final; March 14, 1996), FDA relied on agency experts and technical consultants to develop a broad profile of mammography facilities and to identify the type and cost of the additional equipment and procedures that would be needed to bring the affected facilities into compliance. That analysis found that the proposed rule would impose annualized industry costs of approximately $61.4 million. Upon review of the resulting public comments, FDA has maintained the basic methodology for these estimates, but updated or otherwise revised a number of the input variables.

The full details of the cost estimates for these final regulations are presented in the agency's final Economic Impact Analysis, which is available for review at the Dockets Management Branch and at FDA's home page on the World Wide Web (www.fda.gov) the analysis addresses only those costs that would not have occurred in the absence of these final regulations. The estimates assume that at a minimum mammography facilities are already complying with the agency's current interim regulations and that a typical facility will comply with each requirement of the final regulation by selecting the least costly method of compliance. Current facility compliance levels for the industry were derived for early provisions of the final regulations from published data services or interviews with experts in mammography. The cost estimates are based on a facility cost model that analyzes the inputs to a mammographic examination (e.g., professional time, amortization of fixed equipment costs, variable costs of supplies) and derives the contribution of each activity to the average cost of conducting a mammographic screen. The required capital costs were developed from an industry wide inventory of existing equipment stock, which allowed FDA to estimate the percentage of equipment that will need to be modified or replaced. The compliance cost attributable to equipment requirements was calculated by including the value that this equipment will lose (based on years of remaining asset life) and the cost of retrofitting, if possible. The aggregate costs were modeled over a 10-year analysis period and allocated among the industry sectors based on facility screening volumes. This method allowed FDA to analyze the effect of compliance costs on small volume and large volume facilities.

The analysis projects that yearly expenditures for compliance by mammography facilities will range from a high of $156.2 million during the second year of implementation to $9.5 million during the tenth year, with the variation reflecting the phased implementation dates for the individual requirements. On an annualized basis (over the 10-year period at a 7 percent discount rate), the yearly costs will equal about $38.2 million. Over the full 10-year period, the combined expenditures and lost resources for the largest cost element (replacement of mammography units with units meeting technical or quality assurance standards) will total more than $241 million and contribute approximately $28.5 million in average annual costs (75 percent of the total average annual costs). The other major annual cost components include medical records and reports, $4.6 million; quality assurance systems, $3.4 million; personnel qualifications, $1.6 million; and consumer complaint mechanisms, $0.1 million.

B. Incremental Benefits

The benefits of the final regulations will result from improvements in mammography quality and include: (1) Additional life-years (or quality adjusted life-years (QALY's)) and reduced costs of cancer treatment gained by earlier stage identification of breast cancers, and (2) less anxiety and stress and reduced cost of followup diagnostic mammographic screens and other diagnostic procedures gained by fewer false abnormal screens. While data limitations preclude FDA from developing a precise estimate of the magnitude of these benefits, the agency has constructed an impact model that projects the expected health and cost outcomes under various scenarios of plausible mammography quality levels. This model, which forecasts breast cancer outcomes based on tumor stages at time of initial identification, is summarized below and fully described in the agency's aforementioned final Economic Impact Analysis.

1. Baseline Estimates

The patient population affected by the regulation includes all 79.3 million women age 30 or older. Applying age-specific cancer incidence rates to the number of women in each 10-year age cohort projects approximately 180,600 new breast cancer cases annually, of which about one-quarter may ultimately prove fatal.

About 90 percent of the 25 million mammography procedures performed each year are for screening procedures in asymptomatic patients. Thus, FDA's impact model assumes a base of 22.5 million annual screens and 2.5 million annual diagnostic (or subsequent) mammograms in symptomatic patients. Of the 22.5 million screens, approximately 5 million (22 percent) are for women over the age of 65 and 2.7 million (12 percent) are for women younger than 40. The remaining 14.8 million annual screens are distributed by size of each 10-year age category. The age-specific cancer incidence rates within each age cohort indicate that about 56,900 of the 22,500,000 annual screens are for women with breast cancer and 22,443,100 are for women without breast cancer.

Although the benefits of the rule derive from increases in the quality of mammography, the quality dimensions are very difficult to measure. Each mammogram is unique because each patient is unique and many factors contribute to quality, including those that are not affected by these regulations. While other measures have been suggested (e.g., cancer yield and PPV), FDA's impact model relies on a combination of sensitivity and specificity levels to represent average mammography quality. The sensitivity of any diagnostic test is the proportion of the tested, diseased population that is correctly identified as diseased. Thus, test sensitivity addresses the problem of false negatives. The specificity of a test measures the proportion of nondiseased patients who are correctly identified as not having the disease. Thus, test specificity addresses the problem of false positives.

If both sensitivity and specificity improve toward 100 percent, the proportion of ''incorrect'' mammograms decreases. Although improvements in one measure may come at the expense of decreases in the other, as certain technical changes can tradeoff sensitivity for specificity, FDA finds that the input changes required by this regulation will raise the national average of both measures. Thus, the agency's impact model measures quality improvement as the percent decrease (expressed as a percentage over the current level) in the number of incorrect diagnoses, both false positives and false negatives.

Estimates of the current national average levels of mammography sensitivity and specificity are approximate representations, because they reflect literature examinations based on different patient populations, time periods, and definitions. Current sensitivity measures in community settings have ranged from 53 percent to as high as 90 percent and specificity measures have reached as high as 99 percent. However, several studies indicate that mammography facilities in research/academic settings have sensitivity and specificity measures that exceed most ''typical, community facilities'' by 7 to 13 percent. Based on these studies, FDA's baseline estimates assume that current national levels of sensitivity and specificity average 80 percent and 90 percent, respectively. The calculations use age-specific rates, because breast tissue density varies by age of patient.

The estimated 80 percent sensitivity rate implies that while 45,400 of the estimated 56,900 annually screened women with breast cancer currently receive a true positive result, 11,500 receive a false negative result. Thus, FDA estimates that each year, mammography fails to identify breast cancers in an estimated 11,500 screened women. The agency's impact model, which relies on a distribution of identified cancers by development stage and SEER incidence rates for both screened and nonscreened populations, predicts that about 4,300 of these 11,500 women will die of breast cancer within 20 years. The model implies that perfect mammography would prevent about 1,200 of these fatalities. FDA recognizes that perfect mammographic screening is not yet technologically achievable, but the agency is convinced that mammography sensitivity rates can be significantly improved, thereby avoiding a substantial number of these premature deaths.

Economic literature includes many attempts to place a dollar value on mortality avoidance for the purpose of conducting cost/benefit analysis. A common methodology estimates society's willingness to pay to avoid the risk of a statistical death as evidenced by wage premiums necessary to attract employees to riskier occupations. These data contain considerable variability, but appear to average about $5 million per death avoided. Thus, for illustrative purposes, FDA's analysis assumes a $5 million value to represent the societal benefit of preventing a premature death. The value of a life-year was estimated at $368,000 and the value of a quality-adjusted life-year at $373,000.

FDA also believes that the improved mammography quality gained by the final regulations will significantly reduce the rate of false positive results. The above methodology indicates that 22,443,100 women without breast cancer are screened annually. Consequently, a baseline specificity measure of 90 percent implies that 20,184,600 will receive true negative results, but 2,258,500 others will receive false positive results. FDA estimated the cost of the anxiety and increased stress associated with these false positive screening results by assessing the contribution of psychological well-being to the overall quality of life.

The time between a patient notification of a positive screen result and the subsequent identification through a followup diagnostic mammogram was assumed to take about 1 month. The cost of enduring this anxiety was assumed to detract from the value of a quality-adjusted month value of $31,100, i.e., $373,000 ÷ 12. Research indicates that mental focus and psychological well-being affected by a major life crisis can contribute approximately 8 percent to the overall quality of life. Worries about health, illness, and well-being may account for approximately one-sixth of the stress that would constitute a major life crisis. To assess the potential effect, FDA's impact model assumes that 25 percent of those patients who receive false positive results would be willing to pay about $415 ($31,100 x .08 x .167) to avoid the stress and anxiety of a false positive mammogram.

FDA also found that cancer treatment costs vary by stage of detection, from annual costs of $18,900 for the earliest stage to $50,000 for the latest stage. Other components of FDA's model address patient noncompliance with screening results due to fear or denial. Diagnostic mammography readings were assumed to follow positive initial screens, and additional followup diagnostic procedures were assumed to follow positive diagnostic results and to identify lesions that were present without screening. Based on limited data, FDA's model assumes that a small number of those patients with positive screens do not seek further treatment. Figure 1 illustrates the model components and baseline estimates.

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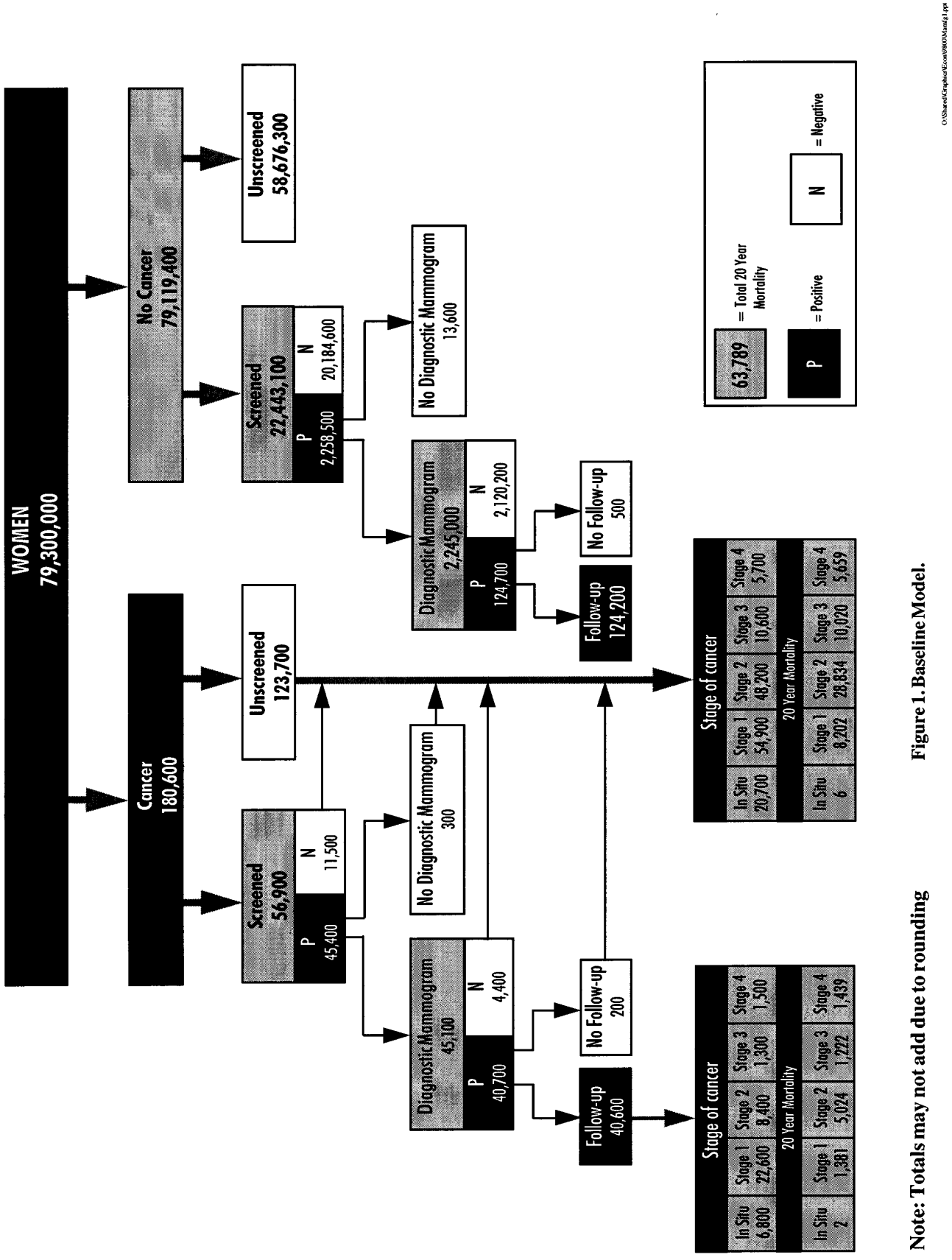

Figure 1. Baseline Model.

Note: Totals may not add due to rounding

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2. Regulatory Impacts

The agency also finds that the impact of these regulations could affect the demand for mammography. One study found a price elasticity of approximately -0.2 for outpatient well care. As the rules will likely raise mammography prices as well as costs, FDA incorporated this price elasticity into its impact model. On the other hand, improved mammography quality will have a positive effect on mammography demand. Assuming that the demand for mammography for a subset of potential patients exhibits a unitary elasticity with respect to quality, FDA's impact model finds that a 5 percent increase in mammography quality would roughly offset the above price-induced decline in demand, with the net change less than .03 percent.

Because of the difficulty in assessing the impact of the regulations on mammography quality, no public comments attempted to quantify the likely health outcomes. Similarly, FDA cannot predict the precise magnitude of the quality improvement that will be generated by these final regulations. FDA believes, however, that the mammography quality improvements will be substantial and that gains as small as 5 percent (i.e., reducing the proportion of incorrect procedures by 5 percent by increasing average sensitivity levels from 80 percent to 81 percent, and specificity levels from 90 to 90.5 percent) would produce substantial net benefits. The results of this analysis are shown in figure 2. For example, when compared to the baseline data (figure 1), the number of earlier cancers detected due to a 5 percent improvement in mammography sensitivity would prevent about 75 women per year from dying of breast cancer within a 20-year period. At $5 million per life saved, the discounted value of this outcome is about $234 million per year. Alternatively, the model shows that a 5 percent quality improvement would bring an annual increase of about 410 discounted QALY's valued at $153 million. Thus, FDA estimates the benefit of avoiding these premature mortalities as ranging from $153 to $233 million per year.

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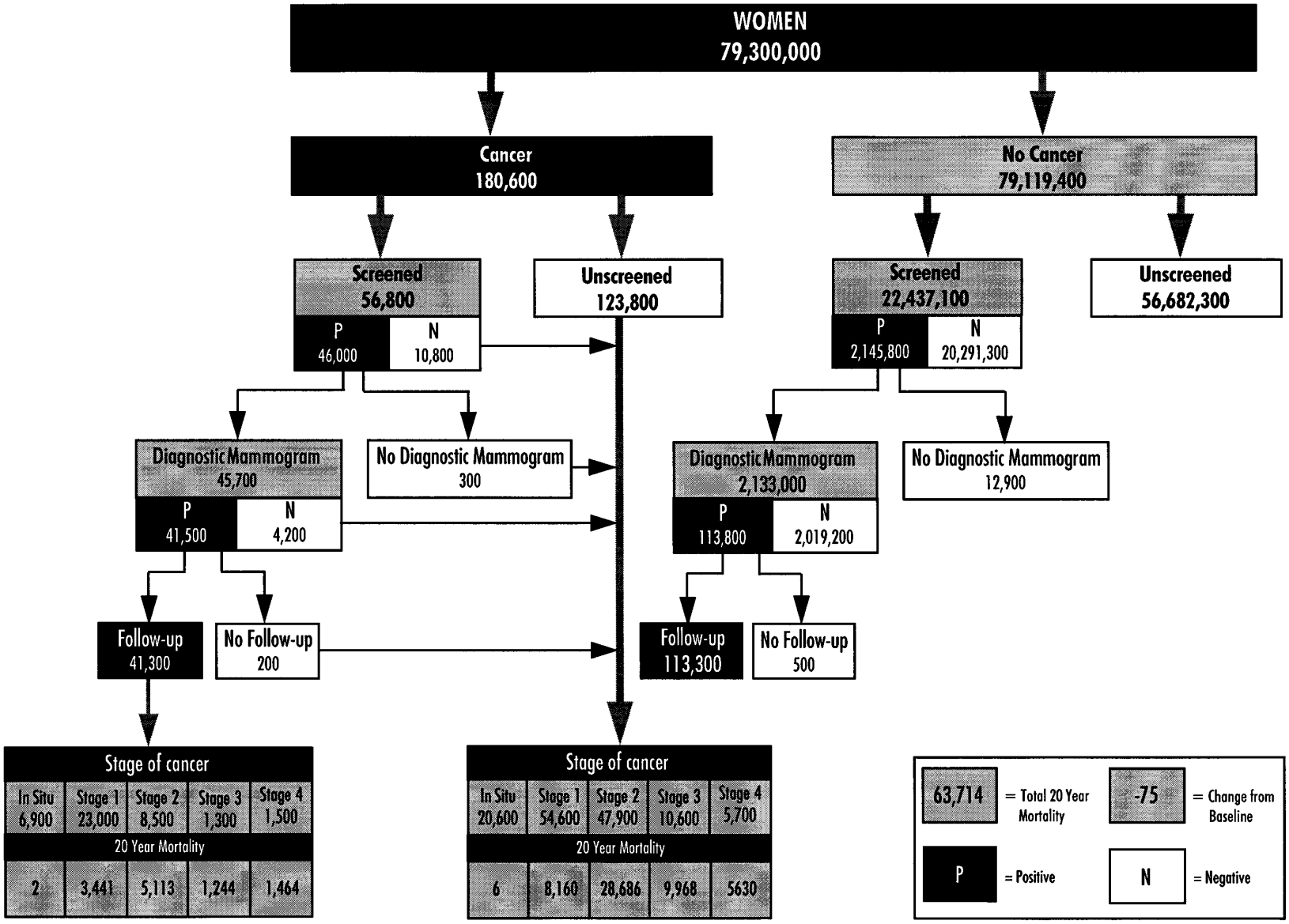

Note: Totals may not add due to rounding

Figure 2. Model with 5-percent quality improvement, and final rule compliance costs.

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A 5 percent quality improvement would also decrease cancer treatment costs by about $1.9 million. In addition, the reduction in false positives would produce less anxiety and stress valued at $12.7 million, and reduced diagnostic costs of $14.5 million. In total, quality improvements of 5 percent would generate annual benefits of from $182 to $263 million, far exceeding the expected annual compliance costs of $38.2 million. From a cost-effectiveness perspective, the cost per QALY would amount to about $20,000. Even if the overall quality improvement were only 2 percent, the estimated annual benefits of the final regulation exceed the estimated annual compliance costs.

C. Small Business Impact

According to the Small Business Administration, any doctor's office, clinic, or hospital with $5 million or less in revenue is considered small. In addition, any not-for-profit enterprise that is independently owned and operated and not dominant in its field is considered small. On this basis, mammography is offered in about 4,800 small doctor's offices or clinics and 5,000 small hospitals, comprising up to 98 percent of all mammography facilities.

FDA recognizes that the nature of these regulations may have a disproportionate effect on very small volume mammography facilities, as fixed costs of compliance for equipment improvements are likely to increase the cost per mammogram for low volume facilities relatively more than for high volume facilities. The cost of a mammogram is expected to increase by 3.4 percent in an average facility and by 4.2 percent in the smallest 10 percent of facilities. However, total revenues are also likely to increase. Overall, the annual net revenues attributable to mammography (gross revenues minus gross costs) are estimated to decline by approximately $1,000 in the smallest 10 percent of facilities, whereas the larger facilities may experience net revenue gains. ERG judged that these smallest facilities would have an increased vulnerability for closure. These results are fully described in the agency's final Economic Impact Analysis.

FDA also examined the effect on small businesses of alternative implementation schedules for this proposal. For example, one alternative would have required an even more elaborate equipment upgrade, effective immediately upon issuance of the regulations. The agency rejected this alternative becauseit would have placed an unnecessary burden on the industry, costing more than $120 million annually. By eliminating some specifications that were marginal to ensuring mammography quality, and phasing in certain requirements to allow for normal replacement of current equipment, the agency substantially reduced the cost of compliance. FDA also considered postponing the implementation of the final equipment requirements by an additional year. This alternative would have reduced the annual compliance costs by $7.1 million, but delay the impact on quality improvements. The final implementation schedule was selected as a reasonable balance between compliance costs and quality improvements. FDA also considered providing an exemption for small facilities in shortage areas, but concluded that the importance of mammography quality made this tradeoff unacceptable, and that a primary objective of MQSA was to ensure quality for all patients. The agency's final Economic Impact Analysis includes a discussion of several additional alternatives.

D. Total Impact of the MQSA

The total compliance costs for all of the regulations implementing the MQSA are the sum of the costs for the interim rules already in place, as well as for the final regulations as estimated above. Thus, to assess the total costs of the MQSA, FDA also estimated the costs of complying with the interim regulations.

Interim regulations implementing the MQSA required facilities to be accredited by an FDA-approved body as a first step towards receiving a certificate. FDA approved the ACR and the States of Iowa, Arkansas, and California to accredit facilities. The standards used by these bodies to accredit facilities were developed by FDA, but are largely based on the standards previously used by the ACR in their voluntary accreditation program. Because the ACR was the only national accreditation body and had already accredited approximately half of the mammography facilities in the country in its voluntary program, the majority of unaccredited facilities applied to the ACR for accreditation in order to continue to provide mammography services. On being notified by the ACR or one of the State bodies that a facility was accredited, FDA issued a certificate to the facility.

Approximately 5,500 facilities had not fully completed the accreditation and certification process by October 1, 1994 and approximately 1,000 accredited facilities were assumed to incur low levels of compliance cost. FDA estimated the costs of compliance with the interim rule by dividing these 6,500 facilities (5,500 unaccredited and 1,000 accredited) into groups with low, moderate, and high levels of noncompliance. Approximately 4,500 of these facilities had completed the accreditation and certification process by the end of the 6-month period of the provisional certificates or required minor improvements to achieve accreditation. These facilities were assumed to have low levels on noncompliance. Approximately 1,500 were able to complete the accreditation and certification process by the end of a 90-day extension of their 6-month provisional certificate. These facilities were assumed to have a moderate level of noncompliance. The remaining approximately 500 facilities were assumed to have a high level of noncompliance.

Discussions with expert consultants and operators of mammography facilities indicated that a low level of noncompliance would typically include minor recordkeeping and personnel training deficiencies. A moderate noncompliance level would typically include (beyond the low level) some quality assurance deficiencies and equipment requiring retrofit. Finally, facilities with high levels of noncompliance would incur costs for replacement of a mammography unit (in addition to ''moderate'' costs less retrofit). Based on this methodology, FDA estimates the annual costs of the interim rule at about $23.4 million. Adding the additional $38.2 million cost attributable to the final rules indicates that the total annual compliance costs of the MQSA are about $61.6 million.

The benefits of the interim rules result from their impact on mammography quality. A poll of industry experts indicated that the interim rules may have improved mammography quality by between 2 and 10 percent. Other reports have estimated that based on 1992 levels of quality, typical community quality levels may have been as much as 13 percent below the quality levels found in academic or research centers. FDA agrees that post-interim levels of quality may be approximately 10 percent lower than those found in typical academic settings, which implies a relative quality gain of 3 percent due to the interim regulations. FDA also found that, given average annual compliance costs of $23.4 million for the interim regulations, a 3.1 percent quality improvement would account for the current level of mammography use (all else being equal). Thus, FDA estimates that the interim regulations have

resulted in an approximate 3 percent increase in mammography quality. With this assumption, FDA's impact model calculates that the overall annual benefits of the interim rule range from $108 to $155 million, including the annual gain of about 44 lives and 242 discounted QALY's.

E. Conclusions

In summary, the final regulations will generate mammography quality increases above those already achieved by the interim regulations. As shown in the summary table, the annual costs of compliance with these final regulations are estimated at $38.2 million. Expected benefits will accrue as a result of fewer breast cancer fatalities due to the earlier detection of lesions and the avoidance of unnecessary surgery. While the magnitude of the expected quality increases are uncertain, an improvement of 5 percent in mammography sensitivity and specificity would result in annual benefits valued at from $178 to $257 million. With respect to all of the MQSA requirements, the annual compliance costs of the combined interim and final regulations equal about $61.5 million, and the annual benefits (assuming total quality increases of 8 percent) range from $284 to $408 million.

TABLE 1.—SUMMARY OF ECONOMIC IMPACTS (MILLION $)

	Interim Rule[1]	Final Rule[2]	Total[3]
Compliance Costs	23.4	38.2	61.6
Benefits	108.2–153.8	181.7–262.7	289.9–416.5
Diagnostic Cost Decreases	9.0	14.5	23.5
Treatment Cost Decreases	1.1	1.9	3.0
Anxiety Cost Decreases	7.8	12.7	20.5
Value of Lives Extended	90.3–135.9	152.6–233.6	242.9–369.5

[1]Assumes 3 percent increase in mammography quality
[2]Assumes 5 percent increase in mammography quality
[3]Assumes 8 percent increase in mammography quality

F. Responses to Comments on the Impact Analysis of the Proposed Regulation

1. Cost Analysis

FDA published a preliminary impact analysis in association with the final regulations on April 3, 1996. Public comments were invited on the methodology and projections included in that analysis.

One comment disagreed with the cost-benefit analysis and stated that the imposition of additional costs would adversely affect public health because fewer women will be able to receive the benefits of mammography.

FDA agrees that additional costs with no concurrent quality improvement may adversely affect mammography access. FDA also recognizes that access without quality is of no public benefit. FDA believes, however, that the assurance of quality resulting from these regulations will overcome any possible negative impacts. This belief is supported by a CDC study on mammography utilization that showed a continued increase in screening mammography examinations under the MQSA interim rules (Ref. 4).

One comment stated that most CEU classes for technologists cost between $75.00 and $100.00 for 6 to 8 credits, and require additional travel expenses. FDA agrees with the estimate provided by this comment. FDA estimated that the cost per hour of technologist's CEU would cost approximately $16.00 per credit hour and used this estimate in its impact analysis. This estimate was based on input from consultants and is within the range presented by this comment.

Numerous comments stated that the **Federal Register** notice for the proposed rule lacked sufficient methodological detail and should have included the cost of each requirement and the per facility or per procedure cost.

FDA agrees that the summary of impacts included in the **Federal Register** did not include detailed methodologies, discussions of assumptions, and sources of data. Nevertheless, as is required, FDA had provided a clear explanation of the calculations used for the cost/benefit analysis in the Full Regulatory Impact Analysis which was available for review at the Dockets Management Branch. Similarly, the agency's final Economic Impact Analysis, which provides substantial detail on the cost estimates is available at the same location that document can also be retrieved from FDA's home page on the World Wide Web (www.fda.gov).

A number of comments asserted that the equipment requirements would mandate the replacement of most mammography units and would increase the cost of these replacement units and that these costs were underestimated by FDA. One comment calculated the cost of replacing 15,000 mammography units, priced at $70,000, at more than $1 billion. The comment also calculated the cost of replacing 5,000 processors (½ of total), priced at $15,000, at $75 million.

FDA disagrees with the assumption that all mammography units in the country (which actually number about 12,000 instead of 15,000) or even most units will have to be replaced in order to meet the final rules. The Economic Impact Analysis that accompanies this final rule includes a detailed discussion on the estimation of the replacement costs. FDA has estimated the costs of the equipment requirements of the proposed rule by estimating replacement and retrofit costs through contacts with mammography equipment manufacturers. For replacements, the analysis considers the lost useful life of the machine. FDA also solicited input on compliance costs from mammography unit manufacturers and project consultants. These manufacturers indicated that not all mammography units would require replacement or retrofit and that prices for the new units would be identical to current prices. Based upon these sources of information, FDA estimated the total costs related to the equipment requirements of the proposed regulations to be approximately $270 million or $35 million in average annual costs (over the 10-year analysis period at a 7 percent discount rate). The agency notes that, after consideration of the public comments and other information, a number of equipment requirements, including those related to processors, were deleted before these regulations were issued. The impact of those deletions was to reduce the total estimated expenditure of meeting the equipment requirements in lost resources to $241 million and the average annual costs over the 10-year analysis period to $28.5 million.

One comment stated that phasing in equipment requirements 5 and 10 years after the effective date of the regulations would significantly increase costs if facilities are required to replace the unit in 5 years and then again in 10 years.

FDA believes that this comment stems from a misinterpretation of the proposal. FDA did not expect facilities to replace units every 5 years. Input on the equipment requirements from manufacturers indicated units would be available almost immediately after the regulations were published that would be able to meet the 5- and 10-year requirements. Thus, if a unit had to be replaced to meet an immediate requirement, a new unit could be selected that would meet the 5- and 10-year requirements as well. The facility would not need to purchase additional replacement units ''every 5 years.'' FDA's purpose in phasing in some requirements 5 and 10 years in the future was to provide time for facilities whose units met the immediate requirements but not the 5- or 10-year requirements to replace those units on their regular replacement schedule. This would decrease the burden by allowing machines to be replaced as they reach the end of their useful life. However, for reasons discussed in the responses to the comments on the equipment requirements, most of the 5-year requirements and all of the 10-year requirements were removed before these final regulations were issued.

Two comments expressed concern that the cost requirements for training every technologist to perform weekly or daily phantom checks were not considered in the impact analysis of the proposed regulations. Another comment estimated that the cost of performing the daily phantom tests for 240 days per year at $0.80 per sheet of film would be an additional $192.00 per unit. Using the estimated 10,800 certified units this would mean an additional cost of $2,073,600 per year.

FDA notes that the weekly phantom tests are identical to those currently being performed monthly under the interim regulations. No additional training costs will be incurred beyond those already included in the cost estimates of the interim regulations. FDA did not include any cost requirements for training to perform the daily phantom checks or for performance of the test because the agency did not propose such a test but merely requested public comment on its possible value. As previously discussed, FDA concluded from the public comments that further studies would be needed to confirm the value of such a test before it was made a regulatory requirement. Because it was not made a regulatory requirement, no costs either for training in its performance or performing the test needed to be included in these cost estimates.

A number of comments stated that FDA underestimated costs by not considering all of the factors that will contribute to increased provider and consumer cost.

FDA's Economic Impact Analysis has attempted to consider all of the factors that will contribute to increased costs from compliance with the final rule. This analysis is available through the Dockets Management Office, as well as the World Wide Web. As these comments did not identify the factors believed to have been overlooked, the agency is unable to give a more specific response.

Numerous comments asserted that the cost of lay notification would significantly increase the costs of mammography. These comments estimated that the cost ranged from $0.78 to $15.00 per notification.

For the proposed rule, FDA used a methodology to estimate the cost of patient notification that is similar to that described in the comments. The Economic Impact Analysis presented an estimate of $0.94 per written notification including 2.5 minutes of an office staff worker's time and cost of postage. However, this proposed requirement was removed from the final rule before it was codified, so these estimated costs will not occur.

A number of comments stated that the increased costs to comply with the final rule will result in facility closings (especially for small-volume facilities and rural facilities) and loss of access. One comment also stated that FDA has not adequately justified the cost of the regulation in the face of reducing access to low income populations.

FDA agrees that it is possible that increased costs of conducting mammography due to these regulations may cause some facilities to close if those facilities are currently not offering high quality mammography. However, FDA disagrees that such an impact has not been adequately explored. FDA has attempted to identify areas of potential access problems and believes that very few patients would be adversely affected if, as is anticipated, few, if any, facilities close as a result of the burdens of the final regulations. When facilities do close, alternate facilities are usually expected to be available within a reasonable distance. The agency also notes that the GAO study cited earlier found that the interim regulations, which had a similar cost impact, had little impact on access. FDA agrees that access for low income women is a potential problem, but does not believe that these regulations will greatly increase this problem. Nevertheless, FDA will monitor this potential outcome to ensure that any adverse impact on underserved populations is minimized.

One comment stated that costs were underestimated because only the incremental costs of nonvoluntary compliance were identified.

FDA disagrees with this comment. The quality standards contained in these regulations reflect standards of good practice, so it would not be surprising to find that many facilities were already complying with them before the regulations went into effect. Where voluntary compliance with regulatory requirements existed prior to implementation of the rule, costs were not included in the agency's Economic Impact Analysis because they are due to the facility's own desire to achieve quality mammography and not to the regulations. FDA agrees that if compliance costs occur only as a result of or in anticipation of a regulation and would be discontinued in its absence, such costs should be considered. However, FDA believes that most mammography facilities did not anticipate the specific regulatory requirements of this rule, and so any past actions to improve quality at their facilities were independent actions on their part.

Several comments noted that the proposal included only costs associated with the proposed regulations and not the interim rule. They stated that the costs and benefits of the entire MQSA should be estimated.

FDA agrees with these comments and has included estimates of the interim impacts for these final regulations.

One comment noted that costs may be understated because FDA assumed the lowest compliance cost. This comment stated that because some facilities would incur higher costs, the overall costs were underestimated.

FDA disagrees with this comment. The agency assumed that each facility would adopt a least-cost compliance strategy, which is standard economic methodology for analysis of regulations as required by Executive Order 12866. While some facilities would have higher costs, other facilities would have lower (or no) costs. Thus, the least-cost method of compliance for the average facility is a reasonable method of estimating industry wide costs. It is possible that this comment misunderstood the methodology used to estimate costs.

One comment stated that FDA has not adequately accounted for decreases in mammography usage due to expected cost increases.

FDA has attempted to address this issue for the final regulations. FDA agrees that cost increases are likely to decrease mammography use, all else being equal, but that perceived increases in mammography quality are likely to offset any negative impact. This issue is discussed above in B.2 and in the Economic Impact Analysis that accompanies the final rule.

One comment asserted that FDA's costs were ''unrealistic,'' rely only on consultant opinion and are, therefore, unreliable.

FDA disagrees with this comment. Cost estimates were derived from an extensive process of site-visits and expert input and no alternative data were included with this comment. The agency's cost methodology is fully detailed in the Economic Impact Analysis.

Several comments noted that specific activities were underestimated. FDA cannot respond to these comments because no supporting data were supplied.

2. Benefits Analysis

A number of comments maintained that FDA overstated the expected improvement in avoiding cancer deaths from the final regulation and that the benefit estimates should be based on scientific literature.

FDA believes that quality improvements in mammography will result in health gains, of which reductions in breast cancer mortality are a major contributor. FDA has attempted to assess the potential quality gains from the requirement of the final rule by reviewing relevant literature and through contact with experts in mammography quality. The Economic Impact Analysis that accompanied the proposed regulations included a detailed and referenced description of the benefits estimate. Similarly, the analysis of impacts for the final regulations include, a comprehensive description of the methodology.

One comment maintained that the final rule was a waste of money because the ACR program has already accomplished a goal of ''reasonably achievable mammographic quality.''

FDA disagrees with this comment. While voluntary accreditation by ACR did much to improve quality in participating facilities, the agency notes that, at the time of passage of the MQSA, less than half of the mammography facilities in the country had sought voluntary accreditation. The MQSA and its implementing regulations have led to the establishment of a uniform minimum set of quality standards to be met by all mammography facilities, including standards in areas not previously covered by the ACR program, and have provided increased assurance that these standards continue to be met between the times of accreditation. As shown in the above impact analysis, the agency believes that the benefits achieved more than compensate for the additional costs.

One comment stated that there has been a significant improvement in the quality of mammography performed under the interim regulations and further maintained that this quality improvement will continue under the final regulations.

FDA agrees with this comment. Quality improvements attributable to the interim regulations are estimated in conjunction with those attributable to the final regulations.

Several comments stated that because sensitivity is defined as the number of true positives divided by the number of true positives plus false negatives, a gain in sensitivity rate would have no effect on the false positive rate.

FDA agrees with these comments. FDA believes that both false negatives and false positives would be reduced by the quality improvements expected from these regulations. Thus, FDA believes that expected quality improvements would be likely to improve both sensitivity and specificity of screening mammography examinations. FDA notes that a typographical error in the analysis of impacts accompanying the proposed regulations may have contributed to these comments.

One comment stated that the discussion on sensitivity confuses the notion that there are inherent tradeoffs between sensitivity and specificity with the mathematical reality that this is not necessarily the case. The respondent believed also that this error may be due to confusing sensitivity with PPV.

FDA recognizes that the sensitivity and the PPV of a diagnostic test are not identical. Nonetheless, FDA believes that sensitivity and specificity provide reasonable quality measures for evaluating these final regulations.

Several comments stated that there is an error in the benefits analysis where it states, ''a five percent gain in sensitivity measurements of 80 percent would indicate a revised sensitivity level of 81 percent (a reduction of the rate of false positives from 20 to 19 percent).'' The comments stated that 5 percent gain to 80 is 84 not 81.

FDA agrees that the description of the impact was not well stated. A 5 percent quality improvement is defined in FDA's analysis as a 5 percent reduction in inaccurate testing results. Thus, if 20 percent of the diseased, screened population are currently not identified, a 5 percent quality improvement would see 19 percent not identified. The 5 percent is actually a 5 percent reduction in the complement of sensitivity.

Numerous comments asserted that the estimated willingness to pay to avoid a statistical loss of life of $5 million was too high and was unsupported.

FDA disagrees with these comments. For illustrative purposes, FDA has quantified the decreased breast cancer mortality potentially resulting from the rule using an average value of $5.0 million per each avoided death. This value is the implied value of society's willingness to pay to avoid the likelihood of an additional death as derived from economic literature, as referenced in the full Economic Impact Analysis. The methodology used to estimate this value is based on wage-premiums necessary to induce workers to accept riskier occupations and is a commonly used approach for estimating the value that society appears to be willing to pay to avoid a statistical death.

Several comments questioned the probability of expected benefits accruing from improvements in specificity. The comments identified this as the area where the greatest cost savings could be realized, and underlined this area as one which should be a target for improvement by the MQSA. Relatively small improvements in specificity could markedly reduce the numbers of false positive results nationwide, resulting in less diagnostic testing.

FDA agrees with these comments. These cost savings were addressed for the proposed regulations and are addressed for these final regulations.

One comment stated that raising the sensitivity of a test results in an increase in the false positives rather than a decrease.

FDA disagrees. The agency finds that quality improvements made to comply with the final rule are likely to improve sensitivity and/or specificity by raising the typical community receiver operating characteristic curve toward the optimum level. That is, quality improvements due to these regulations would change the entire relationship between sensitivity and specificity by improving the production function of mammography. As a result, both measures would be improved by these regulations.

One comment questioned the use of identified cancer stages used in the benefit analysis and noted that there is controversy associated with the impact of ductal carcinoma in situ on health outcomes.

FDA agrees with this comment and adjusted the benefit analysis for the final regulations.

One comment asserted that benefits were overstated because the general trend in mammography was toward higher quality even in the absence of the regulations.

FDA disagrees that the beneficial impact of these regulations has been overstated. Current trends in mammography quality are accounted for in baseline conditions.

Several comments noted areas of potential benefit that were not accounted for in the analysis that accompanied the proposal. These areas include the benefit of increased assurance to patients, the benefits of increased diagnostic quality, and reductions in treatment costs for identified cancers.

FDA agrees with these comments and has included these categories in this final analysis.

One comment stated that references for the benefit analysis were not available. FDA notes that references were included with the Economic Impact Analysis that accompanied the proposed regulations.

One comment noted that the affected population would change over time and that FDA has assumed a static population.

FDA agrees with this comment. FDA notes, however, that forecasting changes in future populations would likely increase the expected benefits because of the age distribution changes expected as the baby boom generation moves into ages of greater risk from breast cancer.

Several comments questioned the assumptions used in FDA's benefit estimation model.

FDA agrees that several of the key assumptions are uncertain. Nevertheless, the agency believes that the absence of scientific certainty does not preclude the development of preamble projections based on reasonably supported amplifying assumptions. The Economic Impact Analysis for these final rules provides sensitivity analyses that demonstrate the effects of modifying a number of these variables.

VI. Paperwork Reduction Act of 1995

A. Information Collection Provisions in the Final Rule

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The following title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Reporting and Recordkeeping Requirements for Mammography Facilities.

Description: The final rule collects information from accrediting bodies and mammography facilities. Under the final rule, each accreditation body is required to submit applications and establish a quality assurance program. Each mammography facility is required to establish and maintain a medical reporting and recordkeeping system, a medical outcomes audit program, a consumer complaint mechanism, and records documenting personnel qualifications.

These information collection requirements apply to accreditation bodies and to mammography facilities. In order to be an approved accreditation body, private nonprofit organizations or State agencies must submit an application to FDA and establish procedures and a quality assurance program. Mammography facilities must obtain and prominently display an FDA-issued certificate or provisional certificate; have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism; and maintain records documenting personnel qualifications. These actions are being taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

Respondent Description: Businesses and other for-profit organizations, nonprofit organizations, Federal, State, and local governments.

FDA estimates the burden of this collection of information as follows:

Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3	6	1	6	60	360		
900.3(b)(3)	10	1	10	60	600	$50	
900.3(c)	4	0.14	0.56	15	8.4		
900.3(e)	1	0.2	0.2	1	0.2		
900.3(f)(2)	1	0.2	0.2	200	40		
900.4(c) and (d)[1]	834	1	834	1	834		
900.4(e)[2]	10,000	1	10,000	8	80,000		
900.4(f)[3]	1,000	1	1,000	14.5	14,500		
900.4(h)[4]	6	1	750	6	4,500		
900.4(i)(2)	1	1	1	1	1		
900.6(c)(1)	1	1	1	1	1		
900.11(b)(2)	25	1	25	2	50		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	10,000	0.0050	50	20	1,000		$1,000
900.12(c)(2)	100	1	100	5	500		
900.12(j)(1)	10	1	10	1	10		
900.12(j)(2)	1	1	1	50	50		
900.15(d)(3)(ii)	10,000	0.0020	20	2	40		$100
900.18(c)	10,000	0.0005	6	2	12		$60

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.18(e)	10	0.1000	1	1	1		$10
TOTAL					102,510	$50	$1,170

[1]Formerly § 900.4(b) under the interim rule.
[2]Formerly § 900.4(d) under the interim rule.
[3]Formerly § 900.4(e) under the interim rule.
[4]Formerly § 900.4(g) under the interim rule.

Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facility Requirements; General Facility Requirements and Personnel Requirements

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)[1]	10,000	1	10,000	1	10,000	
900.11(b)(1)[2]	1,000	1	1,000	1	1,000	
900.12(c)(4)[3]	10,000	1	10,000	1	10,000	
900.12(e)(13)	6,000	52	312,000	0.125	39,000	
900.12(f)	10,000	1	10,000	1	10,000	
900.12(h)	10,000	2	20,000	0.5	10,000	$20,000
TOTAL					82,000	$20,000

[1]Formerly § 900.4(f) under the interim rule.
[2]Formerly § 900.11(c)(1) under the interim rule.
[3]Formerly § 900.12(e)(1) under the interim rule.

Most of this burden is not new, but rather results from requirements continued from the interim rule. FDA estimated the annual burden for reporting and recordkeeping requirements under the interim rule to be 120,944 hours (58 FR 67562 and 67569). The additional requirements contained in these final rules will add 63,566 burden hours to this estimate, resulting in an estimated total annual burden of 184,510 hours.

The burden estimate for this final rule differs from the proposed rule in several respects (see 61 FR 14865 to 14868). First, FDA revised § 900.12(c)(2), which proposed written notification of examination results to all mammography patients. The final rule requires that each facility maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. This revision resulted in the removal of proposed § 900.12(c)(2)(i) from the paperwork burden estimates. Second, FDA revised § 900.12(d)(2), which proposed the specific documentation to be maintained by each facility as part of its quality assurance program. This revision included removing §§ 900.12(d)(2)(i), 900.12(d)(2)(ii) and 900.12(d)(2)(iii) from the final rule and combining §§ 900.12(d)(2) and 900.12(d)(2)(iv) from the proposed rule into § 900.12(d)(2) for the final rule. This revision is reflected in these estimates of the recordkeeping burden. Third, FDA added several reporting and recordkeeping burden estimates that are not new to the final rule, but whose impact was overlooked in the burden estimate for the proposed rule. Also, FDA renumbered some of the provisions for the final rule, due to removal or additions of other provisions; these revisions had no effect on the paperwork burden estimates. The following sections concerning paperwork burden were renumbered: § 900.4(a)(7) in the proposed rule is § 900.4(a)(6) in the final rule, and §§ 900.12(f)(2) and 900.12(f)(4) in the proposed rule are §§ 900.12(f)(1) and 900.12(f)(3) in the final rule, respectively.

B. Comments on the Paperwork Reduction Act Statement

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on the information collection provisions of the proposed rule (April 3, 1996). A small number of comments addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA had underestimated burden or had not considered all of the reporting and recordkeeping requirements.

One comment stated that FDA's Paperwork Reduction Act statement underestimated the time burden on mammography facilities for recordkeeping and reporting. The comment further stated that FDA's estimate of 23,553 hours, which translated into less than 2.5 hours per facility (based on an estimated 10,000 mammography facilities in the United States), was low. The comment asserted that FDA underestimated or ignored the incremental burden on facilities from the interim rule to the final rule. The comment further stated that at least one person at each mammography facility

must understand the final rule. The author of the comment estimated this task at 10 hours per person at each of the estimated 10,000 mammography facilities.

FDA disagrees with this statement in general, but upon review of the burden estimates under the proposed rule FDA has revised some of the time estimates. For example, FDA has added hours to cover § 900.12(e)(3)(13), infection control, because its burden was overlooked under the paperwork burden analysis of the proposed rule.

FDA also agrees that someone in the mammography facility will have to understand the final rule and that it will take some time to develop this understanding. The agency believes, however, that the time estimate suggested by the comment is far too high. This belief is based upon three considerations. First, the basic framework of the requirements has not significantly changed from the interim rule. Many of the additional details in the final rule are taken from policies developed under the interim rule, with which the facilities are already familiar. Because of this overlap, the time required to understand the final rule is less than it would be if they were entirely new. Second, the recordkeeping and reporting burdens are estimated on an annual basis; therefore, each estimate is stated as an average time per year. Whatever burden there would be in understanding the new regulations would be primarily a one-time burden. If an individual spends x hours the first year developing an understanding of the regulations, the time required in the second and subsequent years will be much less than x because the person will already be familiar with them. The average time per year for understanding the regulations thus would be only a small fraction of x. Third, in compliance with the Paperwork Reduction Act, it is the time burden for reporting and recordkeeping that is being estimated. Thus, only the time required to understand the new reporting and recordkeeping requirements, not to understand the total requirements, would properly be included in these estimates. The combined effect of these three factors, the agency believes, reduces the time burden for understanding the requirements that should be included in these estimates significantly. The burden for understanding each requirement has been included in the individual burden estimates for that requirement.

One comment stated that FDA had not estimated any burden for compliance with proposed § 900.12(f), which requires each facility to implement a medical outcomes audit. The author of the comment estimated that the burden of such a requirement would require at least 10 hours of an interpreting physician's time at each of the estimated 10,000 mammography facilities. Several other comments also stated that proposed § 900.12(f) was an undue burden on freestanding facilities. The comments discussed the difficulty in tracking down and obtaining all biopsy and consultation outcomes. One comment noted the lack of evidence that outcome measurement contributes to improved care.

FDA understands the difficulty with tracking outcomes data but such data are critical in assessing the quality of mammography at facilities. FDA also notes that most of the requirements in § 900.12(f) do not require any additional reporting or recordkeeping burden beyond what was required under the interim rule.

One comment also asserted that FDA had failed to include the time burden for proposed § 900.12(g), which adds requirements for mammography of patients with breast implants. The comment stated that FDA should have estimated the time burden related to scheduling patients with implants, documenting patients with implants, and requiring the presence of an appropriately trained interpreting physician onsite during mammography of women with implants. The author of the comment estimated that the above would require an additional 10 to 20 hours of reporting and recordkeeping at each mammography facility.

As discussed previously, FDA has changed the proposed requirement that each facility should inquire whether a patient has an implant at the time of scheduling to a requirement in the final rule that each facility shall inquire as to whether the woman has an implant prior to the examination. The final rule also eliminated the requirement that an interpreting physician be present. Even under the proposal, the additional recordkeeping time would have been minimal and the revision in the final rule gives the facility flexibility in determining when and how the information is collected for the patient's record. All facilities maintain patient records with information such as address, telephone number, insurance information, and medical history. The additional time to ask a yes or no question on implants and record the answer is negligible.

Another comment stated that FDA had failed to estimate the additional requirements and documentation associated with personnel requirements in proposed § 900.12(a). The comment estimated that additional documentation requirements would necessitate at least 5 hours of additional time for approximately 1,000 medical physicists, and approximately ¼ hour for each mammography facility.

FDA acknowledges that § 900.12(a) contains some increases in the required level of personnel training and experience from the interim rule. However, FDA did not include any recordkeeping burden estimates for the personnel requirements under either the interim or final rules because the agency believes that it is usual and customary practice for mammography facilities to keep records of the qualifications of their employees.

Although this position makes moot the question of the amount of time required for recordkeeping related to these requirements, FDA would like to note that there are factors that the author of the comment may not have been aware of that make the estimates in the comment excessive. Most changes in the personnel qualifications are only increases in the amounts of the interim requirements. In such cases there is no additional recordkeeping burden. It requires no more effort, for example, under the final rule, to keep a letter in a doctor's records indicating that he or she had 3 months of training in mammography during residency that it did, under the interim rule, to keep a letter indicating he or she had 2 months of such training.

For most of the new personnel requirements in the final rule, such as the continuing experience requirements for technologists and physicists, the information that bears on whether these requirements are met often already exists in the form of various work records. All that is needed is to place a copy or summary in each person's file.

The remaining new standard establishes an initial requirement of a minimum level of education and training for medical physicists. FDA believes that the majority of physicists providing services to mammography facilities will have exceeded this level in meeting the requirement that the medical physicist be board-certified, State licensed, or State approved, which was retained from the interim rule. In such cases, the agency intends to minimize the burden by accepting the documentation of board approval, State licensure, or State approval (in States whose standards for approval exceed the minimum level) as adequate evidence that the second requirement is also met.

Physicists approved by States that require a level of qualification for approval lower than that in the second

requirement will have to provide additional documentation but the time required is likely to be significantly less than the 5 hours estimated in the comment. More importantly, as this is an initial requirement, it will be a one time burden. To be compared with the other burden estimates, it must be averaged over the physicists's entire career, which could be 30 years or longer.

Again, because keeping records of personnel qualifications is usual and customary practice, FDA has not included this in the burden estimates. The agency notes, however, for the reasons discussed above, that the comment greatly overestimates the time required for the new recordkeeping.

One comment stated that virtually all of the requirements in the proposed rule duplicate requirements of accreditation bodies and noted that FDA inspectors require much of the same personnel documentation required by the ACR.

FDA notes that the author of the comment has misunderstood the nature of the accreditation system required under the MQSA. The requirements of the FDA-approved accreditation bodies are not established by those bodies but rather are FDA-established quality standards that the accreditation bodies, as a condition of their approval, must ensure are met by the facilities they accredit. Thus, there is only one set of requirements, not two or more duplicate sets, and the actions identified in the comment are mandated by the legislation in order to increase the likelihood that quality mammography will be consistently achieved.

Several comments asserted that the proposed rule would create an unnecessary amount of paperwork that would ultimately take away from time with patients. One comment asserted that the reporting requirements would necessitate a computer system and additional clerical support.

FDA has attempted to limit the paperwork burden to only those recordkeeping and reporting requirements necessary to ensure that facilities meet minimum quality standards. As discussed above, FDA has also reduced the paperwork burden of the final rule by removing several reporting and recordkeeping requirements from the final rule. The agency believes that the paperwork impact, as estimated in Tables 1 and 2, is not unreasonable in view of the benefits to be gained from the quality standards that made the recordkeeping and reporting necessary.

A number of comments asserted that proposed § 900.12(c)(2), which would have required written notification of mammographic examination results to all mammography patients, would cost time and postage expenses and would generate much paperwork. Some comments asserted that this practice would be redundant for patients with referring physicians who could explain the results.

FDA has revised § 900.12(c)(2) to require that each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. FDA has allowed for increased flexibility in the notification of patients by allowing written or other notification by either the mammography facility or the referring physician. FDA believes that some form of patient notification is a standard of good practice that is currently followed voluntarily by virtually all mammography facilities, so the burden of this requirement will fall only on those few facilities who are not currently meeting such a standard. The flexibility of notification method allowed under the revision of § 900.12(c)(2) will make the burden minimal even for these facilities.

Several comments asserted that proposed § 900.12(h), which requires the development of a consumer complaint mechanism, was unnecessary. The comments stated that all complaints should be handled on an individual basis at each facility according to the protocol of that facility. One comment asserted that the proposed rule would be very costly in terms of staff time and materials.

This comment has misinterpreted the requirements of § 900.12(h), which gives facilities the flexibility to develop their own consumer complaint mechanism in the manner they feel most appropriate. The requirement that each facility must maintain records of each serious complaint over the last 3 years should be of minimal burden to facilities and would only necessitate a file including the appropriate correspondence by the complainant, facility, and accrediting body. Many facilities already have some form of consumer complaint mechanism and would not incur significant additional burden by meeting the requirements of the final rule.

One comment agreed with proposed § 900.12(c)(4)(ii), which states that facilities must transfer mammographic films and records to other facilities or the patient at the patient's request, but stated that it was not economical or practical to copy films for the sake of keeping them in the patient's medical record.

FDA notes that § 900.12(c)(4)(ii) does not require that a facility maintain copies of a patient's medical records if the patient has asked to have them transferred elsewhere. The facility is free to determine for itself whether it is desirable to copy films for its own records.

Several comments stated that proposed § 900.4(c), which requires clinical image review as part of the accreditation and reaccreditation process, would be extremely costly and time-consuming. This burden includes the time and expense of choosing the images and having them copied and mailed. Another comment supported clinical image review as the best approach for a performance-based standard, but also stated that it would be costly and time-consuming.

FDA notes that Congress specifically required clinical image review as part of the accreditation and reaccreditation process (42 U.S.C. 263b((e)(1)(B)(i)), because clinical image review is necessary to ensure high quality mammography. While it may appear that the complexity of the process, and thus of the burden, has increased due to the increased detail in the final rule, these details are presently being followed as policy by the accreditation bodies so, in fact, there is no additional burden. The agency further notes that facilities are not required to copy the films before sending them for review. Only original films are reviewed and these are returned to the facility after the review is complete.

Several comments stated that § 900.12(e)(13), requiring facilities to establish an infection control procedure including documentation after each cleaning, would create needless paperwork and would not affect quality assurance.

FDA has included an additional paperwork burden estimate for this requirement in the final rule. Under § 900.12(e)(13), facilities are required to establish and comply with a system for cleaning and disinfecting equipment as needed. Although there is no evidence that blood-borne pathogens have been transmitted from patient to patient during mammography, there is a theoretical possibility of such a transmission. That agency believes the time required is justified to ease concerns about such a possibility, concerns that in some cases may cause patients to refuse to undergo mammography examinations and thus possibly lose the life-saving benefit of early detection of breast cancer.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve,

modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Appendix

Excerpts from Chapter 4 of AHCPR's "Quality Determinants of Mammography;" Guidelines for Communicating Test Results

As noted previously, FDA recommends that mammography facilities utilize the AHCPR'S guidelines in ''Quality Determinants of Mammography'' with respect to written notification of results to patients. The pertinent information from Chapter 4 of those guidelines is reprinted here for ease of reference. The symbol [R] indicates that the AHCPR document provides an additional reference or references at that point.

COMMUNICATING RESULTS

RECOMMENDATION: The referring health care provider and the interpreting physician should be sensitive, supportive, and appropriate in communicating results, as well as prompt and accurate. (B)

STRONG RECOMMENDATION: An appropriate professional at the mammography facility, usually an interpreting physician, should send the woman's health care provider a written report documenting the specific findings, follow up recommendations, and the name of the interpreting physician. The facility should directly telephone the referring provider if the result is suspicious for cancer. (B)

STRONG RECOMMENDATION: The mammography facility personnel should give the woman written notification of the results of her mammography and other breast imaging, either on site or by mail. The results should be in simple language, document the name of the interpreting physician, be given in a timely fashion, and include further steps to be taken. (B)

RECOMMENDATION: If a facility accepts women who have no health care provider, facility personnel should give the woman a list of qualified providers who are willing to provide care. The name, address, and phone number of the provider chosen should be recorded, if possible (C).

STRONG RECOMMENDATION: The facility personnel should directly telephone the woman who has no health care provider if the result is suspicious for cancer (B).

Many women believe that mammography results are normal if they are not contacted after their examination. This impression that ''no news is good news'' can have serious adverse consequences for women with an abnormal examination. The interpreting physician, the referring health care provider, and the woman are all responsible for ensuring that mammography results are communicated in an effective and timely manner and that recommendations are carried out. Timely communication is necessary whether results are normal or abnormal (Table 3).

An increasing number of mammography facilities have begun to report both normal and abnormal results directly to the woman. This can be accomplished without disrupting the woman's relationship with her referring provider. Studies have shown that direct communication of results to the woman by the mammography facility produces a dramatic improvement in compliance with follow recommendations [R]. Traditional communication procedures, where the facility communicates only with the referring provider, result in inadequate compliance with follow up recommendations [R].

Problems in communicating abnormal results have included confusion concerning the appropriate steps to be taken; inappropriate or insensitive communication, resulting in avoidable anxiety and confusion; delay in receipt of results; and failure to communicate results to the woman at all—for example, when reports are misfiled or filed unread. These problems have caused delays in diagnosis and treatment, with consequences that include limited treatment options and death [R]. Providing results directly to the woman is a sound risk-management procedure, reducing the prospect of medicolegal complications for both the interpreting physician and the referring health care provider [R].

TABLE 3.—REPORTING OF RESULTS BY MAMMOGRAPHY FACILITY

Outcome of Mammography Examination and Recommendation for Followup	Communication to Women—Oral (Onsite or by Telephone)	Communication to Women—Write (Onsite or Sent by Mail)	Phone Communication to Health Care Provider in Addition to Standard Report	Always Necessary Written Report to Health Care Provider
Normal	Optional	Strongly Recommended	None	Strongly Recommended
Abnormal: schedule additional imaging and/or ultrasonography	Recommended[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
a) On line[1]	Optional[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
b) Off line[1]				
Abnormal: short-interval followup	Optional	Strongly recommended	Optional	Strongly recommended
Abnormal: Biopsy	Optional strongly recommended for self-referred women	Strongly recommended[4]	Strongly recommended	Strongly recommended

[1] For an online study, the interpreting physician is present and reads the mammogram while the patient is there. For an offline study, the mammogram may be read after the woman leaves so the interpreting physician does not have to be present.

[2] For any patient for whom additional views or ultrasonography are recommended, a telephone call or discussion onsite with the patient may precede the written letter when the studies are to be performed immediately or within 2 days at that mammography facility. However, the results of the original and additional studies must be provided to the woman in writing.

[3] A telephone call from the mammography facility to the woman's designated physician or other health care provider is recommended. For self-referred patients, the telephone call should be made to the woman herself.

[4] For any patient without a direct referral, the mammography facility may wish to send the letter via registered or certified mail.

NOTE: Strong recommendations deal with elements of mammography that the panel considers essential to good practice. Recommendations deal with elements of mammography that the panel considers attainable in most but not all cases. Options are statements of a less compelling nature that cannot be justified as recommendations.

Communicating normal results directly to the woman as soon as possible eliminates anxiety, reinforces the woman's role as a responsible participant in the process, reminds the woman of the importance of regular screening, and is a quality assurance safeguard. Effective communication is most crucial when results are abnormal and additional imaging or other follow up is required. If findings are abnormal, the written results should detail steps the woman should take next.

Any written communication must have language that is carefully constructed to impart results without causing undue anxiety, to promote a relationship between the woman and a health care provider, and to encourage the woman to take the next step. [Note—the AHCPR publication provides several examples of letters for communicating results directly to women.]

Mammography facilities may accept self-requesting and self-referred women for mammography. Interpreting physicians have additional responsibilities for ensuring the effective communication of results for these women.

- Self-requesting woman. This woman comes for mammography on her own initiative but is able to name a personal physician or health care provider. Whether the woman is having screening or diagnostic mammography, the interpreting physician should document that the designated provider accepts responsibility for the woman's breast care before sending out the mammography report. In cases where the provider declines to accept the mammography report from the mammography facility, the facility should treat the woman as if she were self-referred.
- Self-referred woman. This is a woman who comes for mammography but has no personal health care provider or for whom the provider declines responsibility. Whether the woman is having screening or diagnostic mammography, the interpreting physician assumes responsibility for the woman's breast care, including education, physical examination, and communication of mammography results directly to the patient in understandable language. Mammography facility personnel should give the woman a list of qualified providers. If the woman chooses a provider from a list provided by the mammography facility, the interpreting physician should ensure that the chosen clinician will assume responsibility for the woman's breast care. Although self-referral has improved access to mammography, it has increased the responsibilities of the interpreting physician and created more possibilities for failure to communicate abnormal results.

STRONG RECOMMENDATION: At the time of the examination, mammography facility personnel should inform all women of the time period in which they will receive their results and of the possibility that prior films may need to be obtained. The woman should also be instructed to call the mammography facility or her health care provider if she does not receive her results within the stated time period. The facility should report results to the woman's provider and to the woman within the shortest practical time period. (B)

RECOMMENDATION: The facility should use its best efforts to send a report to the referring health care provider and to send results to the woman as soon as possible, usually within 10 business days. The reporting period should not exceed 30 days. (B)

STRONG RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires needle or open biopsy to the referring (or designated) health care provider's office in a timely manner. (B)

RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires additional views and/or ultrasonography in a timely manner to the referring (or designated) health care provider's office. (B)

OPTIONAL: The interpreting physician or the referring (or designated) health care provider may telephone the woman directly to explain abnormal findings, their significance, and recommended next steps. (B)

Mammography facility personnel should telephone the referring or designated health care provider because the written report may not reach the provider or may not arrive in time for the provider to respond to questions from the patient. A telephone call also enables the provider to ask questions about the report and to discuss follow up options with the interpreting physician [R].

When mammography results are abnormal, a telephone call to the woman's designated health care provider before a report is sent may identify and resolve any vagueness in the provider-patient status. For a self-requesting woman with an abnormal finding, this call will significantly reduce the chance that she will slip through the cracks.

If the woman does not have a provider or if the provider declines to accept the report, the interpreting physician or designee should call the woman directly to explain the result and the recommended next steps. This telephone communication is in addition to the written report and should offer the option to have the results explained in person. Information should not be left on an answering machine or given to another individual without the woman's express prior permission. Particularly for the woman without a referring provider, the mammography facility may choose to send written notification of abnormal results by certified mail or with return receipt requested. Mammography facility personnel should document the communication to the referring provider or the woman in the woman's medical record. Recommended reporting is outlined on Table 3.''

Chapter 6 of the AHCPR document also provides more information on the communication responsibilities of the interpreting physician.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ries, L. A. G., B. A. Miller, and B. F. Hankey, et al. (Eds.), ''SEER Cancer Statistics Review, 1973–1991,'' National Cancer Institute, NIH Pub. No. 94–2789, Bethesda, MD, 1994.

2. AHCPR, ''Quality Determinants of Mammography,'' AHCPR Pub. No. 95–0632, October, 1994.

3. U.S. GAO, ''Mammography Services Initial Impact of New Federal Law Has Been Positive,'' GAO/HEHS–96–17, October, 1995.

4. Linver, M. N., J. R. Osuch, R. J. Brenner, and R. A. Smith, ''The Mammography Audit: A Primer for the Mammography Quality Standards Act (MQSA),'' *American Journal of Radiology*, 1995; 165:19–25.

5. CDC, ''Use of Mammography Services by Women Aged ≤ 65 Years Enrolled in Medicare—United States, 1995–1993,'' 1995; 44:777–781.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 900 are amended as follows:

PART 16—REGULATORY HEARINGS BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 21 U.S.C. 41–40, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364; 15 U.S.C. 1451–1461, 28 U.S.C. 2112.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding entries for §§ 900.7 and 900.14 to read as follows:

§ 716.1 Scope.

* * * * *

(b) * * *

(2) Regulatory provisions:

* * * * *

§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900.14, relating to suspension or revocation of a mammography certificate.

* * * * *

3. 21 CFR Part 900 is revised to read as follows:

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Sec.

Subpart B—Quality Standards and Certification

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

Subpart A—Accreditation

§ 900.1 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart A of this part establishes procedures whereby an entity can apply to become a Food and Drug Administration (FDA)-approved accreditation body to accredit facilities to be eligible to perform screening or diagnostic mammography services. Subpart A further establishes requirements and standards for accreditation bodies to ensure that all mammography facilities under the jurisdiction of the United States are adequately and consistently evaluated for compliance with national quality standards for mammography. Subpart B of this part establishes minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. The regulations set forth in this part do not apply to facilities of the Department of Veterans Affairs.

§ 900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accreditation body* or *body* means an entity that has been approved by FDA under § 900.3(d) to accredit mammography facilities.

(b) *Action limits* or *action levels* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

(c) *Adverse event* means an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Adverse events include but are not limited to:

(1) Poor image quality;

(2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

(3) Use of personnel that do not meet the applicable requirements of § 900.12(a).

(d) *Air kerma* means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 radian (rad) = 114 roentgens (R) of exposure.

(e) *Breast implant* means a prosthetic device implanted in the breast.

(f) *Calendar quarter* means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

(g) *Category I* means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

(h) *Certificate* means the certificate described in § 900.11(a).

(i) *Certification* means the process of approval of a facility by FDA to provide mammography services.

(j) *Clinical image* means a mammogram.

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

(l) *Continuing education unit* or *continuing education credit* means one contact hour of training.

(m) *Contact hour* means an hour of training received through direct instruction.

(n) *Direct instruction* means:

(1) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(2) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(o) *Direct supervision* means that:

(1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

(p) *Established operating level* means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

(q) *Facility* means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(r) *First allowable time* means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The ''first allowable time'' may vary with the certifying body.

(s) *FDA* means the Food and Drug Administration.

(t) *Interim regulations* means the regulations entitled ''Requirements for Accrediting Bodies of Mammography Facilities'' (58 FR 67558–67565) and ''Quality Standards and Certification Requirements for Mammography Facilities'' (58 FR 67565–67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808–49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

(u) *Interpreting physician* means a licensed physician who interprets mammograms and who meets the requirements set forth in § 900.12(a)(1).

(v) *Kerma* means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(w) *Laterality* means the designation of either the right or left breast.

(x) *Lead interpreting physician* means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of § 900.12(d) through (f). The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

(y) *Mammogram* means a radiographic image produced through mammography.

(z) *Mammographic Modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(bb) *Mammography equipment evaluation* means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in § 900.12(b) and (e).

(cc) *Mammography medical outcomes audit* means a systematic collection of mammography results and the comparison of those results with outcomes data.

(dd) *Mammography unit* or *units* means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(ee) *Mean optical density* means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(ff) *Medical physicist* means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in § 900.12(a)(3).

(gg) *MQSA* means the Mammography Quality Standards Act.

(hh) *Multi-reading* means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

(ii) *Patient* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

(jj) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

(kk) *Phantom image* means a radiographic image of a phantom.

(ll) *Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(mm) *Positive mammogram* means a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.''

(nn) *Provisional certificate* means the provisional certificate described in § 900.11(b)(2).

(oo) *Qualified instructor* means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of § 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

(pp) *Quality control technologist* means an individual meeting the requirements of § 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(qq) *Radiographic equipment* means X-ray equipment used for the production of static X-ray images.

(rr) *Radiologic technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements set forth in § 900.12(a)(2).

(ss) *Serious adverse event* means an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(tt) *Serious complaint* means a report of a serious adverse event.

(uu) *Standard breast* means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

(vv) *Survey* means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(ww) *Time cycle* means the film development time.

(xx) *Traceable to a national standard* means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

§ 900.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accreditation bodies.

(b) *Application for initial approval.* (1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

(2) Following receipt of the request, FDA will provide the applicant with additional information to aid in submission of an application for approval as an accreditation body.

(3) The applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and, if the applicant is not a State agency, evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization);

(ii) Detailed description of the accreditation standards the applicant will require facilities to meet and a discussion substantiating their equivalence to FDA standards required under § 900.12;

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing accreditation and reaccreditation clinical image review in accordance with § 900.4(c), random clinical image reviews in accordance with § 900.4(f), and additional mammography review in accordance with § 900.12(j);

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for initiating and performing onsite visits to facilities;

(E) Procedures for assessing facility personnel qualifications;

(F) Copies of the accreditation application forms, guidelines, instructions, and other materials the applicant will send to facilities during the accreditation process, including an accreditation history form that requires each facility to provide a complete history of prior accreditation activities and a statement that all information and data submitted in the application is true and accurate, and that no material fact has been omitted;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for suspending or revoking a facility's accreditation;

(J) Policies and procedures that will ensure processing of accreditation applications and renewals within a timeframe approved by FDA and assurances that the body will adhere to such policies and procedures; and

(K) A description of the applicant's appeals process for facilities contesting adverse accreditation status decisions.

(iv) Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;

(v) Description of the applicant's electronic data management and analysis system with respect to accreditation review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;

(vii) Fee schedules with supporting cost data;

(viii) Statement of policies and procedures established to avoid conflicts of interest or the appearance of conflicts of interest by the applicant's board members, commissioners, professional personnel (including reviewers of clinical and phantom images), consultants, administrative personnel, and other representatives of the applicant;

(ix) Statement of policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body;

(x) Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells, or distributes;

(xi) Description of the applicant's consumer complaint mechanism;

(xii) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xiii) Any other information as may be required by FDA.

(c) *Application for renewal of approval.* An approved accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of a body's approval, the body shall inform FDA, at the address given in § 900.3(b)(1), of its intent to seek renewal.

(2) FDA will notify the applicant of the relevant information, materials, and supporting documentation required under § 900.3(b)(3) that the applicant shall submit as part of the renewal procedure.

(3) At least 6 months before the date of expiration of a body's approval, the applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with § 900.3(c)(2).

(4) No later than July 28, 1998 any accreditation body approved under the interim regulations published in the **Federal Register** of December 21, 1993 (58 FR 67558), that desires to continue to serve as an accreditation body under the final regulations shall apply for renewal of approval in accordance with the procedures set forth in paragraphs (c)(1) through (c)(3) of this section.

(5) Any accreditation body that does not plan to renew its approval shall so notify FDA at the address given in paragraph (b)(1) of this section at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial and renewed approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the accreditation standards the applicant will require facilities to meet are substantially the same as the quality standards published under subpart B of this part.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be rectified within a specified time period. If the deficiencies are not rectified to FDA's satisfaction within the specified time period, the application for approval as an accreditation body may be rejected.

(3) FDA shall notify the applicant whether the application has been approved or denied. That notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(6) If FDA does not reach a final decision on a renewal application in accordance with this paragraph before the expiration of an accreditation body's current term of approval, the approval will be deemed extended until the agency reaches a final decision on the application, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of authority.* An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA, at the address in § 900.3(b)(1), at least 9 months before relinquishing such authority.

(f) *Transfer of records.* An accreditation body that does not apply for renewal of accreditation body approval, is denied such approval by FDA, or relinquishes its accreditation authority and duties before expiration of its term of approval, shall:

(1) Transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

(2) Notify, in a manner and time period approved by FDA, all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* An accreditation body's term of approval is for a period not to exceed 7 years. FDA may limit the scope of accreditation authority.

§ 900.4 Standards for accreditation bodies.

(a) *Code of conduct and general responsibilities.* The accreditation body shall accept the following responsibilities in order to ensure safe and accurate mammography at the facilities it accredits and shall perform these responsibilities in a manner that ensures the integrity and impartiality of accreditation body actions.

(1)(i) When an accreditation body receives or discovers information that suggests inadequate image quality, or upon request by FDA, the accreditation body shall review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether or not the facility's practice poses a serious risk to human health. Such reviews are in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities.

(ii) If review by the accreditation body demonstrates that a problem does exist with respect to image quality or other aspects of a facility's compliance with quality standards, or upon request by FDA, the accreditation body shall require or monitor corrective actions, or suspend or revoke accreditation of the facility.

(2) The accreditation body shall inform FDA as soon as possible but in no case longer than 2 business days after becoming aware of equipment or practices that pose a serious risk to human health.

(3) The accreditation body shall establish and administer a quality assurance (QA) program that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section. Such quality assurance program shall:

(i) Include requirements for clinical image review and phantom image review;

(ii) Ensure that clinical and phantom images are evaluated consistently and accurately; and

(iii) Specify the methods and frequency of training and evaluation for clinical and phantom image reviewers, and the bases and procedures for removal of such reviewers.

(4) The accreditation body shall establish measures that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the body's behalf. Such individuals who review clinical or phantom images under the provisions of paragraphs (c) and (d) of this section or who visit facilities under the provisions of paragraph (f) of this section shall not review clinical or phantom images from or visit a facility with which such individuals maintain a financial relationship, or when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.

(5) The accreditation body may require specific equipment performance or design characteristics that FDA has approved. However, no accreditation body shall require, either explicitly or implicitly, the use of any specific brand of imaging system or component, measuring device, software package, or other commercial product as a condition for accreditation by the body, unless FDA determines that it is in the best interest of public health to do so.

(i) Any representation, actual or implied, either orally, in sales literature, or in any other form of representation, that the purchase or use of a particular product brand is required in order for any facility to be accredited or certified under § 900.11(b), is prohibited, unless FDA approves such representation.

(ii) Unless FDA has approved the exclusive use and promotion of a particular commercial product in accordance with this section, all products produced, distributed, or sold by an accreditation body or an organization that has a financial or other relationship with the accreditation body that may be a conflict of interest or have the appearance of a conflict of interest with the body's accreditation functions, shall bear a disclaimer stating that the purchase or use of such products is not required for accreditation or certification of any facility under § 900.11(b). Any representations about such products shall include a similar disclaimer.

(6) When an accreditation body denies accreditation to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body for the facility to contest the decision.

(7) No accreditation body may establish requirements that preclude facilities from being accredited under § 900.11(b) by any other accreditation body, or require accreditation by itself under MQSA if another accreditation body is available to a facility.

(8) The accreditation body shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted under § 900.3(d).

(9) An accreditation body shall establish procedures to protect confidential information it collects or receives in its role as an accreditation body.

(i) Nonpublic information collected from facilities for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to FDA or its duly designated representatives, including State agencies, without the consent of the facility;

(ii) Nonpublic information that FDA or its duly designated representatives, including State agencies, share with the accreditation body concerning a facility that is accredited or undergoing accreditation by that body shall not be further disclosed except with the written permission of FDA.

(b) *Monitoring facility compliance with quality standards.* (1) The accreditation body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those in this subpart and in subpart B of this part.

(2) The accreditation body shall notify a facility regarding equipment, personnel, and other aspects of the facility's practice that do not meet such standards and advise the facility that such equipment, personnel, or other aspects of the practice should not be used by the facility for activities within the scope of part 900.

(3) The accreditation body shall specify the actions that facilities shall take to correct deficiencies in equipment, personnel, and other aspects of the practice to ensure facility compliance with applicable standards.

(4) If deficiencies cannot be corrected to ensure compliance with standards or if a facility is unwilling to take corrective actions, the accreditation body shall immediately so notify FDA, and shall suspend or revoke the facility's accreditation in accordance with the policies and procedures described under § 900.3(b)(3)(iii)(I).

(c) *Clinical image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review clinical images from each facility accredited by the body at least once every 3 years.

(2) Requirements for clinical image attributes. The accreditation body shall use the following attributes for all clinical image reviews, unless FDA has approved other attributes:

(i) Positioning. Sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning.

(ii) Compression. Compression shall be applied in a manner that minimizes the potential obscuring effect of overlying breast tissue and motion artifact.

(iii) Exposure level. Exposure level shall be adequate to visualize breast structures. Images shall be neither underexposed nor overexposed.

(iv) Contrast. Image contrast shall permit differentiation of subtle tissue density differences.

(v) Sharpness. Margins of normal breast structures shall be distinct and not blurred.

(vi) Noise. Noise in the image shall not obscure breast structures or suggest the appearance of structures not actually present.

(vii) Artifacts. Artifacts due to lint, processing, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present.

(viii) Examination identification. Each image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(A) Name of the patient and an additional patient identifier.

(B) Date of examination.

(C) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section shall be used to identify view and laterality.

(D) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(E) Technologist identification.

(F) Cassette/screen identification.

(G) Mammography unit identification, if there is more than one unit in the facility.

(3) Scoring of clinical images. Accreditation bodies shall establish and administer a system for scoring clinical images using all attributes specified in paragraphs (c)(2)(i) through (c)(2)(viii) of this section or an alternative system that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section. The scoring system shall include an evaluation for each attribute.

(i) The accreditation body shall establish and employ criteria for acceptable and nonacceptable results for each of the 8 attributes as well as an overall pass-fail system for clinical image review that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(ii) All clinical images submitted by a facility to the accreditation body shall be reviewed independently by two or more clinical image reviewers.

(4) Selection of clinical images for review. Unless otherwise specified by FDA, the accreditation body shall require that for each mammography unit in the facility:

(i) The facility shall submit craniocaudal (CC) and mediolateral oblique (MLO) views from two mammographic examinations that the facility produced during a time period specified by the accreditation body;

(ii) Clinical images submitted from one such mammographic examination for each unit shall be of dense breasts (predominance of glandular tissue) and the other shall be of fat-replaced breasts (predominance of adipose tissue);

(iii) All clinical images submitted shall be images that the facility's interpreting physician(s) interpreted as negative or benign.

(iv) If the facility has no clinical images meeting the requirements in paragraphs (c)(4)(i) through (c)(4)(iii) of this section, it shall so notify the accreditation body, which shall specify alternative clinical image selection methods that do not compromise care of the patient.

(5) Clinical image reviewers. Accreditation bodies shall ensure that all of their clinical image reviewers:

(i) Meet the interpreting physician requirements specified in § 900.12(a)(1);

(ii) Are trained and evaluated in the clinical image review process, for the types of clinical images to be evaluated by a clinical image reviewer, by the accreditation body before designation as clinical image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security and return to the facility of all clinical images received and to ensure completion of all clinical image reviews by the body in a timely manner. The accreditation body shall return all clinical images to the facility within 60 days of their receipt by the body, with the following exceptions:

(i) If the clinical images are needed earlier by the facility for clinical purposes, the accreditation body shall cooperate with the facility to accommodate such needs.

(ii) If a clinical image reviewer identifies a suspicious abnormality on an image submitted for clinical image review, the accreditation body shall ensure that this information is provided to the facility and that the clinical images are returned to the facility. Both shall occur no later than 10 business days after identification of the suspected abnormality.

(7) Notification of unsatisfactory image quality. If the accreditation body determines that the clinical images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(d) *Phantom image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review phantom images from each facility accredited by the body at least once every 3 years.

(2) Requirements for the phantom used. The accreditation body shall require that each facility submit for review phantom images that the facility produced using a phantom and methods of use specified by the body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(3) Scoring phantom images. The accreditation body shall use a system for scoring phantom images that has been approved by FDA in accordance with § 900.3(b) and (d) or paragraph (a)(8) of this section.

(4) Phantom images selected for review. For each mammography unit in the facility, the accreditation body shall require the facility to submit phantom images that the facility produced during a time period specified by the body.

(5) Phantom image reviewers. Accreditation bodies shall ensure that all of their phantom image reviewers:

(i) Meet the requirements specified in § 900.12(a)(3) or alternative requirements established by the accreditation body and approved by FDA in accordance with § 900.3 or paragraph (a)(8) of this section;

(ii) Are trained and evaluated in the phantom image review process, for the types of phantom images to be evaluated by a phantom image reviewer, by the accreditation body before designation as phantom image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any phantom image and provide information to the facility for use in improving its phantom image quality with regard to the significant deficiencies identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security of all phantom images received and to ensure completion of all phantom image reviews by the body in a timely manner. All phantom images that result in a failure of accreditation shall be returned to the facility.

(7) Notification measures for unsatisfactory image quality. If the accreditation body determines that the phantom images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(e) *Reports of mammography equipment evaluation, surveys, and quality control.* The following requirements apply to all facility equipment covered by the provisions of subparts A and B:

(1) The accreditation body shall require every facility applying for accreditation to submit:

(i) With its initial accreditation application, a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in § 900.12(e).

(ii) Prior to accreditation, a survey that was performed no earlier than 6 months before the date of application for accreditation by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.

(2) The accreditation body shall require that all facilities undergo an annual survey to ensure continued compliance with the standards referenced in paragraph (b) of this section and to provide continued oversight of facilities' quality control programs as they relate to such standards. The accreditation body shall require for all facilities that:

(i) Such surveys be conducted annually;

(ii) Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and

(iii) Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.

(3) The accreditation body shall review and analyze the information required in this section and use it to identify necessary corrective measures for facilities and to determine whether facilities should remain accredited by the body.

(f) *Accreditation Body Onsite Visits and Random Clinical Image Reviews.* The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation. The accreditation body shall submit annually to FDA, at the address given in § 900.3(b)(1), 3 copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

(1) Onsite visits. (i) Sample size. Annually, each accreditation body shall visit at least 5 percent of the facilities it accredits. However, a minimum of 5 facilities shall be visited, and visits to no more than 50 facilities are required, unless problems identified in paragraph (f)(1)(i)(B) of this section indicate a need to visit more than 50 facilities.

(A) At least 50 percent of the facilities visited shall be selected randomly.

(B) Other facilities visited shall be selected based on problems identified through State or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or FDA.

(C) Before, during, or after any facility visit, the accreditation body may require that the facility submit to the body for review clinical images, phantom images, or any other information relevant to applicable standards in this subpart and in subpart B of this part.

(ii) Visit plan. The accreditation body shall conduct facility onsite visits according to a visit plan that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section, unless otherwise directed by FDA in particular circumstances. At a minimum, such a plan shall provide for:

(A) Assessment of overall clinical image QA activities of the facility;

(B) Review of facility documentation to determine if appropriate mammography reports are sent to patients and physicians as required;

(C) Selection of a sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner specified by the accreditation body and approved by FDA that does not compromise care of the patient as a result of the absence of the selected images from the facility;

(D) Verification that the facility has a medical audit system in place and is correlating films and pathology reports for positive cases;

(E) Verification that personnel specified by the facility are the ones actually performing designated personnel functions;

(F) Verification that equipment specified by the facility is the equipment that is actually being used to perform designated equipment functions;

(G) Verification that a consumer complaint mechanism is in place and that the facility is following its procedures; and

(H) Review of all factors related to previously identified concerns or concerns identified during that visit.

(2) Clinical image review for random sample of facilities. (i) Sample size. In addition to conducting clinical image reviews for accreditation and reaccreditation for all facilities, the accreditation body shall conduct clinical image reviews annually for a randomly selected sample as specified by FDA, but to include at least 3 percent of the facilities the body accredits. Accreditation bodies may count toward this random sample requirement all facilities selected randomly for the onsite visits described in paragraph (f)(1)(i)(A) of this section. Accreditation bodies shall not count toward the random sample requirement any facilities described in paragraph (f)(1)(i)(B) of this section that were selected for a visit because of previously identified concerns.

(ii) Random clinical image review. In performing clinical image reviews of the random sample of facilities, accreditation bodies shall evaluate the same attributes as those in paragraph (c) of this section for review of clinical images for accreditation and reaccreditation.

(iii) Accreditation bodies should not schedule random clinical image reviews at facilities that have received notification of the need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous 6 months.

(iv) Selection of the random sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner, specified by the accreditation body and approved by FDA under § 900.3(d) or paragraph (a)(8) of this section, that does not compromise care of the patient as a result of the absence of the selected images from the facility.

(g) *Consumer complaint mechanism.* The accreditation body shall develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility. Such system shall have been approved by FDA in accordance with§ 900.3(d) or paragraph (a)(8) of this section. Accordingly, all accreditation bodies shall:

(1) Provide a mechanism for all facilities it accredits to file serious unresolved complaints with the accreditation body;

(2) Maintain a record of every serious unresolved complaint received by the body on all facilities it accredits for a period of at least 3 years from the date of receipt of each such complaint;

(h) *Reporting and recordkeeping.* All reports to FDA specified in paragraphs (h)(1) through (h)(4) of this section shall be prepared and submitted in a format

and medium prescribed by FDA and shall be submitted to a location and according to a schedule specified by FDA. The accreditation body shall:

(1) Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated, in a manner and at a time specified by FDA.

(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(3) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies, suspends, or revokes accreditation, and the reason(s) for such action;

(4) Submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them;

(5) Provide to FDA other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

(i) *Fees.* Fees charged to facilities for accreditation shall be reasonable. Costs of accreditation body activities that are not related to accreditation functions under 42 U.S.C. 263b are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different facilities.

(2) At FDA's request, accreditation bodies shall provide financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees. Such material shall be provided to FDA in a manner and time period specified by the agency.

§ 900.5 Evaluation.

FDA shall evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives. The evaluation shall include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under the provisions of § 900.6.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5, or through other means, that an accreditation body is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) *Major deficiencies.* If FDA determines that an accreditation body has failed to perform a major accreditation function satisfactorily, has demonstrated willful disregard for public health, has violated the code of conduct, has committed fraud, or has submitted material false statements to the agency, FDA may withdraw its approval of that accreditation body.

(1) FDA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify facilities accredited or seeking accreditation by it that its approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that an accreditation body has demonstrated deficiencies in performing accreditation functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, FDA shall notify the body that it has a specified period of time to take particular corrective measures directed by FDA or to submit to FDA for approval the body's own plan of corrective action addressing the minor deficiencies. FDA may place the body on probationary status for a period of time determined by FDA, or may withdraw approval of the body as an accreditation body if corrective action is not taken.

(1) If FDA places an accreditation body on probationary status, the body shall notify all facilities accredited or seeking accreditation by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems.

(3) If FDA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the accreditation body. The accreditation body shall notify all facilities accredited or seeking accreditation by it of its loss of FDA approval, within a time period and in a manner approved by FDA.

(c) *Reapplication by accreditation bodies that have had their approval withdrawn.* (1) A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If FDA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, FDA may reinstate approval of the accreditation body.

(3) FDA may request additional information or establish additional conditions that must be met by a former accreditation body before FDA approves the reapplication.

(4) FDA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud or willful disregard of public health.

§ 900.7 Hearings.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval or reapproval of accreditation bodies, withdrawal of approval of accreditation bodies, or rejection of a proposed fee for accreditation shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body. The appeals process shall be specified in writing by the accreditation body and shall have been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

(c) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeals process may appeal to FDA for reconsideration in accordance with § 900.15.

§§ 900.8–900.9 [Reserved]

Subpart B—Quality Standards and Certification

§ 900.10 Applicability.

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide mammography

services, with the exception of the Department of Veterans Affairs.

§ 900.11 Requirements for certification.

(a) *General.* After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

(b) *Application.* (1) *Certificates.* (i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

(2) *Provisional certificates.* (i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(2) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

(ii) Following the agency's receipt of the accreditation body's decision that a facility has submitted the required information, FDA may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of § 900.11(b)(2)(i). A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.

(3) *Extension of provisional certificate.* (i) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body, or other entity designated by FDA, a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

(ii) The accreditation body shall forward the request, with its recommendation, to FDA within 2 business days after receipt.

(iii) FDA may issue a 90-day extension for a provisional certificate upon determination that the extension meets the criteria set forth in 42 U.S.C. 263b(c)(2).

(iv) There can be no renewal of a provisional certificate beyond the 90-day extension.

(c) *Reinstatement policy.* A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.

(1) Unless prohibited from reinstatement under § 900.11(c)(4), a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally certified or certified;

(B) Name of previous owner/lessor;

(C) FDA facility identification number assigned to the facility under its previous certification; and

(D) Expiration date of the most recent FDA provisional certificate or certificate; and

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity designated by FDA, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

(2) FDA may issue a provisional certificate to the facility if:

(i) The accreditation body or other entity designated by FDA notifies the agency that the facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

(ii) FDA determines that the facility has taken sufficient corrective action since the lapse of, denial of renewal, or revocation of its previous certificate.

(3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

(4) If a facility's certificate was revoked on the basis of an act described in 41 U.S.C. 263b(i)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

§ 900.12 Quality standards.

(a) *Personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

(1) Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

(i) Initial qualifications. Unless the exemption in paragraph (a)(1)(iii)(A) of this section applies, before beginning to interpret mammograms independently, the interpreting physician shall:

(A) Be licensed to practice medicine in a State;

(B)(*1*) Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

(*2*) Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section;

(C) Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate

representative of the training institution; and

(D) Unless the exemption in paragraph (a)(1)(iii)(B) of this section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(ii) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

(A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

(C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

(D) Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

(iii) Exemptions. (A) Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999 are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

(B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

(iv) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

(A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall:

(*1*) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

(*2*) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

(*3*) The interpretations required under paragraph (a)(1)(iv)(A)(*1*) or (a)(1)(iv)(A)(*2*) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.

(B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

(2) Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(i) General requirements. (A) Be licensed to perform general radiographic procedures in a State; or

(B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and

(ii) Mammography requirements. Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(iii) Continuing education requirements. (A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(B) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

(D) Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of

continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

(E) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

(iv) Continuing experience requirements. (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of October 28, 1997 whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

(3) *Medical physicists.* All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:

(i) Initial qualifications. (A) Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and

(B)(*1*) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;

(*2*) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(*3*) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999 experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section; or

(ii) Alternative initial qualifications. (A) Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

(B) Prior to the April 28, 1999 have:

(*1*) A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,

(*2*) Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,

(*3*) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

(iii) Continuing qualifications. (A) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

(B) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of October 28, 1997 whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period on a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(iv) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications, as follows:

(A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

(B) Medical physicists who fail to meet the continuing experience requirement of paragraph (a)(3)(iii)(B) of this section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(4) *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

(b) *Equipment.* Regulations published under §§ 1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements.

(1) *Prohibited equipment.* Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in § 1020.31(f)(3) of this chapter.

(2) *General.* All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

(3) *Motion of tube-image receptor assembly.* (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

(4) *Image receptor sizes.* (i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(5) *Beam limitation and light fields.* (i) All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

(ii) For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(6) *Magnification.* (i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification valve within the range of 1.4 to 2.0.

(7) *Focal spot selection.* (i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

(8) *Compression.* All mammography systems shall incorporate a compression device.

(i) Application of compression. Effective October 28, 1999 each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

(ii) Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for ''spot compression'') may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

(9) *Technique factor selection and display.* (i) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliapere (mA) and/or time) shall be available.

(ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

(10) *Automatic exposure control.* (i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(11) *X-ray film.* The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(12) *Intensifying screens.* The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

(13) *Film processing solutions.* For processing mammography films, the facility shall use chemical solutions that

are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(14) *Lighting.* The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

(15) *Film masking devices.* Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

(c) *Medical records and mammography reports*—(1) *Contents and terminology.* Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination;

(iii) The name of the interpreting physician who interpreted the mammogram;

(iv) Overall final assessment of findings, classified in one of the following categories:

(A) ''Negative:'' Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(B) ''Benign:'' Also a negative assessment;

(C) ''Probably Benign:'' Finding(s) has a high probability of being benign;

(D) ''Suspicious:'' Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) ''Highly suggestive of malignancy:'' Finding(s) has a high probability of being malignant;

(v) In cases where no final assessment category can be assigned due to incomplete work-up, ''Incomplete: Need additional imaging evaluation'' shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

(vi) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) *Communication of mammography results to the patient.* Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. If assessments are ''Suspicious'' or ''Highly suggestive of malignancy'' and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section, in addition to a written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

(3) *Communication of mammography results to health care providers.* When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is ''Suspicious'' or ''Highly suggestive of malignancy,'' make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(3)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request or on behalf of, by the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

(5) *Mammographic image identification.* Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(i) Name of patient and an additional patient identifier.

(ii) Date of examination.

(iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(b) or § 900.4(a)(8) shall be used to identify view and laterality.

(iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(v) Technologist identification.

(vi) Cassette/screen identification.

(vii) Mammography unit identification, if there is more than one unit in the facility.

(d) *Quality assurance—general.* Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

(1) *Responsible individuals.* Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

(A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

(B) Participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment

evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.

(iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.

(2) *Quality assurance records.* The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

(e) *Quality assurance—equipment*—(1) *Daily quality control tests.* Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within + 0.15 of the established operating level.

(iii) The density difference shall be within + 0.15 of the established operating level.

(2) *Weekly quality control tests.* Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than + 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than ± 0.05 from the established operating level.

(3) *Quarterly quality control tests.* Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

(4) *Semiannual quality control tests.* Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(iii) Compression device performance. (A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 1999 the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (47 pounds).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic exposure control performance. (A) The AEC shall be capable of maintaining film optical density within ± 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ± 0.30 of the average under phototimed conditions can be produced.

(B) After October 28, 1999 the AEC shall be capable of maintaining film optical density (OD) within ± 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

(ii) Kilovoltage peak (kVp) accuracy and reproducibility. (A) The kVp shall be accurate within + 5 percent of the indicated or selected kVp at:

(*1*) The lowest clinical kVp that can be measured by a kVp test device;

(*2*) The most commonly used clinical kVp;

(*3*) The highest available clinical kVp, and

(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(iii) Focal spot condition. Until October 28, 1999 focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 1999 facilities shall evaluate focal spot condition only by determining the system resolution.

(A) System Resolution. (*1*) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(*2*) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall

edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(*3*) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

(*4*) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(*5*) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(B) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.

TABLE 1

Focal Spot Tolerance Limit		
Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width(mm)	Length(mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

(iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of § 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

TABLE 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

(v) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(vi) Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

(vii) X-ray field/light field/image receptor/compression paddle alignment. (A) All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

(C) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(viii) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(ix) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(x) Radiation output. (A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 1999 the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(xi) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) *Quality control tests—other modalities.* For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

(7) *Mobile Units.* The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(8) *Use of test results.* (i) After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in paragraphs (e)(1), (e)(2), (e)(4)(ii), (e)(4)(iii), (e)(5)(i), (e)(5)(iii), (e)(5)(v), (e)(5)(vi), (e)(6), or (e)(7) of this section;

(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

(9) *Surveys.* (i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.

(ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.

(v) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(10) *Mammography equipment evaluations.* Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(11) *Facility cleanliness.* (i) The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

(ii) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(12) *Calibration of air kerma measuring instruments.* Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of + 6 percent (95 percent confidence level) in the mammography energy range.

(13) *Infection control.* Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(f) *Quality assurance-mammography medical outcomes audit.* Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) *General requirements.* Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the

mammograms taken prior to the diagnosis of a malignancy.

(2) *Frequency of audit analysis.* The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999 whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) *Reviewing interpreting physician.* Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the followup.

(g) *Mammographic procedure and techniques for mammography of patients with breast implants.* (1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

(h) *Consumer compliant mechanism.* Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

(4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

(i) *Clinical image quality.* Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

(j) *Additional mammography review and patient notification.* (1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.

§ 900.13 Revocation of accreditation and revocation ofaccreditation body approval.

(a) *FDA action following revocation of accreditation.* If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

(b) *Withdrawal of FDA approval of an accreditation body.* (1) If FDA withdraws approval of an accreditation body under § 900.6, the certificates of facilities previously accredited by such body shall remain in effect for up to 1 year from the date of the withdrawal of approval, unless FDA determines, in order to protect human health or because the accreditation body fraudulently accredited facilities, that the certificates of some or all of the facilities should be revoked or suspended or that a shorter time period should be established for the certificates to remain in effect.

(2) After 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by the agency, the affected facilities must obtain accreditation from another accreditation body, or from another entity designated by FDA.

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the owner, operator, or any employee of the facility:

(1) Has been guilty of misrepresentation in obtaining the certificate;

(2) Has failed to comply with the standards of § 900.12;

(3) Has failed to comply with reasonable requests of the agency or the accreditation body for records, information, reports, or materials that FDA believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that;

(1) The failure to comply with required standards presents a serious risk to human health;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

(c) If FDA suspends a certificate in accordance with paragraph (b) of this section:

(1) The agency shall provide the facility with an opportunity for an informal hearing under part 16 of this chapter not later than 60 days from the effective date of this suspension;

(2) The suspension shall remain in effect until the agency determines that:

(i) Allegations of violations or misconduct were not substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The facility's certificate is revoked in accordance with paragraph (d) of this section;

(d) After providing a hearing in accordance with paragraph (c)(1) of this section, the agency may revoke the facility's certificate if the agency determines that the facility:

(1) Is unwilling or unable to correct violations that were the basis for suspension; or

(2) Has engaged in fraudulent activity to obtain or continue certification.

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

(a) The appeals procedures described in this section are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by FDA. Agency decisions to suspend or revoke certificates that are already in effect will be handled in accordance with § 900.14.

(b) Upon learning that a facility has failed to become accredited or reaccredited, FDA will notify the facility that the agency is unable to certify that facility without proof of accreditation.

(c) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body, in accordance with § 900.7. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from FDA.

(d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42 CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ–240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

§ 900.16 Appeals of denials of certification.

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a faciity that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

§ 900.17 [Reserved]

§ 900.18 Alternative requirements for § 900.12 quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuing quality mammography as the standard it proposes to replace, and

(2) The proposed alternative:

(i) Is too limited in its applicability to justify an amendment to the standard; or

(ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and

(3) The granting of the alternative is in keeping with the purposes of 42 U.S.C. 263b.

(b) *Applicants for alternatives.* (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of § 900.12.

(2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of § 900.12(a).

(3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of § 900.12(b) and (e).

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Director, Division of Mammography Quality and Radiation Programs (HFZ–240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The application for approval of an alternative standard shall include the following information:

(1) Identification of the original standard for which the alternative standard is being proposed and an explanation of why the applicant is proposing the alternative;

(2) A description of the manner in which the alternative is proposed to deviate from the original standard;

(3) A description, supported by data, of the advantages to be derived from such deviation;

(4) An explanation, supported by data, of how such a deviation would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard;

(5) The suggested period of time that the proposed alternative standard would be in effect; and

(6) Such other information required by the Director to evaluate and act on the application.

(d) *Ruling on applications.* (1) FDA may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice shall state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice shall also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard shall be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the **Federal Register**. The notice shall state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.

(3) Summaries of the approval of alternative standards, including information on their nature and number, shall be provided to the National Mammography Quality Assurance Advisory Committee.

(4) All applications for approval of alternative standards and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications shall be available for public disclosure in the Dockets Management Branch, excluding patient identifiers and confidential commercial information.

(e) *Amendment or extension of an alternative standard.* An application for amending or extending approval of an alternative standard shall include the following information:

(1) The approval number and the expiration date of the alternative standard;

(2) The amendment or extension requested and the basis for the amendment or extension; and

(3) An explanation, supported by data, of how such an amendment or extension would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* (1) Except as provided in paragraphs (f)(2) and (f)(3) of this section, any approval of an alternative standard, amendment, or extension may be implemented only by the entity to which it was granted and under the terms under which it was granted. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(2) When an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard.

(3) The agency may extend the alternative standard to other entities when FDA determines that expansion of the approval of the alternative standard would be an effective means of promoting the acceptance of measures to improve the quality of mammography. All such determinations will be publicized by appropriate means.

(g) *Withdrawal of approval of alternative requirements.* FDA shall amend or withdraw approval of an alternative standard whenever the agency determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when FDA determines that such action is necessary to prevent an imminent health hazard.

Dated: September 25, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

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